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LEGAL COMPILATION: STATUTES AND LEGISLATIVE HISTORY, EXECUTIVE ORDERS, REGULATIONS, GUIDELINES AND REPORTS. E. PESTICIDES. VOLUME II

Environmental Protection Agency
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THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Legal Compilation

Statutes and Legislative History
Executive Orders
Regulations
Guidelines and Reports

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JANUARY 1973

William D. Ruckelshaus
Administrator

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FOREWORD

It has been said that America is like a gigantic boiler in that once the fire is lighted, there are no limits to the power it can generate. Environmentally, the fire has been lit!

With a mandate from the President and an aroused public concern over the environment, we are experiencing a new American Revolution, a revolution in our way of life. The era which began with the industrial revolution is over and things will never be quite the same again. We are moving slowly, perhaps even grudgingly at times, but inexorably into an age when social, spiritual and aesthetic values will be prized more than production and consumption. We have reached a point where we must balance civilization and nature through our technology.

The U.S. Environmental Protection Agency, formed by Reorganization Plan No. 3 of 1970, was a major commitment to this new ethic. It exists and acts in the public's name to ensure that due regard is given to the environmental consequences of actions by public and private institutions.

In a large measure, this is a regulatory role, one that encompasses basic, applied, and effects research; setting and enforcing standards; monitoring; and making delicate risk-benefit decisions aimed at creating the kind of world the public desires.

The Agency was not created to harass industry or to act as a shield behind which man could wreak havoc on nature. The greatest disservice the Environmental Protection Agency could do to American industry is to be a poor regulator. The environment would suffer, public trust would diminish, and instead of free enterprise, environmental anarchy would result.

It was once sufficient that the regulatory process produce wise and well-founded courses of action. The public, largely indifferent to regulatory activities, accepted agency actions as being for the "public convenience and necessity." Credibility gaps and cynicism make it essential not only that today's decisions be wise and well-founded but that the public know this to be true. Certitude, not faith, is de rigueur.

In order to participate intelligently in regulatory proceedings, the citizen should have access to the information available to the agency. EPA's policy is to make the fullest possible disclosure of information, without unjustifiable expense or delay, to any interested party. With this in mind, the EPA Compilation of Legal Authority was produced not only for internal operations of EPA, but as a service to the public, as we strive together to lead the way, through the law, to preserving the earth as a place both habitable by and hospitable to man.

WILLIAM D. RUCKELSHAUS,
Administrator
U.S. Environmental Protection Agency

PREFACE

Reorganization Plan No. 3 of 1970 transferred 15 governmental units with their functions and legal authority to create the U.S. Environmental Protection Agency. Since only the major laws were cited in the Plan, the Administrator, William D. Ruckelshaus, requested that a compilation of EPA legal authority be researched and published.

The publication has the primary function of providing a working document for the Agency itself. Secondarily, it will serve as a research tool for the public.

A permanent office in the Office of Legislation has been established to keep the publication updated by supplements.

It is the hope of the EPA that this set will assist in the awesome task of developing a better environment.

MARY LANE REED WARD GENTRY, J.D.
Assistant Director for Field Operations
Office of Legislation
U.S. Environmental Protection Agency

ACKNOWLEDGEMENT

The idea of producing a compilation of the legal authority of EPA was conceived and commissioned by William D. Ruckelshaus, Administrator of EPA. The production of this compilation involved the cooperation and effort of numerous sources, both within and outside the Agency. The departmental libraries at Justice and Interior were used extensively; therefore we express our appreciation to Marvin P. Hogan, Librarian, Department of Justice; Arley E. Long, Land & Natural Resources Division Librarian, Department of Justice; Frederic E. Murray, Assistant Director, Library Services, Department of the Interior.

For exceptional assistance and cooperation, my gratitude to: Gary Baise, formerly Assistant to the Administrator, currently Director, Office of Legislation, who first began with me on this project; A. James Barnes, Assistant to the Administrator; K. Kirke Harper, Jr., Special Assistant for Executive Communications; John Dezzutti, Administrative Assistant, Office of Executive Communications; Roland O. Sorensen, Chief, Printing Management Branch, and Jacqueline Gouge and Thomas Green, Printing Management Staff; Ruth Simpkins, Janis Collier, Wm. Lee Rawls, Peter J. McKenna, James G. Chandler, Jeffrey D. Light, Randy Mott, Thomas H. Rawls, John D. Whittaker, John M. Himmelberg, Dana W. Smith, and Linda L. Payne, and a beautiful staff who gave unlimited effort; and to many others behind the scenes who rendered varied assistance.

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INSTRUCTIONS

The goal of this text is to create a useful compilation of the legal authority under which the U.S. Environmental Protection Agency operates. These documents are for the general use of personnel of the EPA in assisting them in attaining the purposes set out by the President in creating the Agency. This work is not intended and should not be used for legal citations or any use other than as reference of a general nature. The author disclaims all responsibility for liabilities growing out of the use of these materials contrary to their intended purpose. Moreover, it should be noted that portions of the Congressional Record from the 92nd Congress were extracted from the "unofficial" daily version and are subject to subsequent modification.

EPA Legal Compilation consists of the Statutes with their legislative history, Executive Orders, Regulations, Guidelines and Reports. To facilitate the usefulness of this composite, the Legal Compilation is divided into the eight following chapters:

A. General
B. Air
C. Water
D. Solid Waste
E. Pesticides
F. Radiation
G. Noise
H. International

PESTICIDES

The chapter labeled "Pesticides" and color coded green contains the legal authority of the Agency as it applies to pesticide pollution abatement. It is well to note that any law which is applicable to more than one chapter of the Compilation will appear in each of the chapters; however, its legislative history will be cross-referenced into the "General" chapter where it is printed in full.

SUBCHAPTERS

Statutes and Legislative History

For convenience, the Statutes are listed throughout the Compilation by a one-point system, i.e., 1.1, 1.2, 1.3, etc., and Legislative History begins wherever a letter follows the one-point system. Thusly, any 1.1a, 1.1b, 1.2a, etc., denotes the public laws comprising the 1.1, 1.2 statute. Each public law is followed by its legislative history. The legislative history in each case consists of the House Report, Senate Report, Conference Report (where applicable), the Congressional Record beginning with the time the bill was reported from committee.

Example:

1.1 The Federal Insecticide, Fungicide, and Rodenticide Acts, as amended, 7 U.S.C. §§135–135k (1970).
    1.1a The Insecticide Act, April 26, 1910, P.L. 61–152, 36 Stat. 331.
        (1) Senate Committee on Agriculture and Forestry, S. REP. No. 436, 61st Cong., 2d Sess. (1910).
        (2) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 990, 61st Cong., 2d Sess. (1910).
        (3) Congressional Record, Vol. 45 (1910):
            (a) April 4: Debated, amended and passed Senate, pp. 4204–4206;
            (b) April 18: Debated, amended and passed House, pp. 4914–4920;
            (c) April 19: Senate agrees to House amendments, p. 4959.

This example not only demonstrates the pattern followed for legislative history, but indicates the procedure where only one section of a public law appears. You will note that the Congressional Record cited pages are only those pages dealing with the discussion and/or action taken pertinent to the section of law applicable to EPA. In the event there is no discussion of the pertinent section, only action or passage, then the asterisk (*) is used to so indicate, and no text is reprinted in the Compilation. In regard to the situation where only one section of a public law is applicable, then only the parts of the report dealing with same are printed in the Compilation.

Secondary Statutes

Many statutes make reference to other laws and rather than have this manual serve only for major statutes, these secondary statutes have been included where practical. These secondary statutes are indicated in the table of contents to each chapter by a bracketed cite to the particular section of the major act which made the reference.

Citations

The United States Code, being the official citation, is used throughout the Statute section of the Compilation.

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1.4	The Public Health Service Act, as amended, 42 U.S.C. §241, 243, 246, 264 (1970).	Reorg. Plan No. 3 of 1970.
1.5	Special Packaging of Household Substances for the Protection of Children, 15 U.S.C. §1471 *et seq.* (1970).	In first section of Act, direct reference is made to both FIFRA and the Federal Food, Drug, and Cosmetic Act, section over which we were given authority through Reorg. Plan No. 3 of 1970.
1.6	Hearings: Presiding Employees: Powers and Duties; Burden of Proof; Evidence; Records as a Basis of Decision, 5 U.S.C. §556(c) (1966).	Referred to in the FIFRA at §135b and FD&C Act at §246a(d) (5).
1.7	Record on Review and Enforcement of Agency Orders, as amended, 28 U.S.C. §2112 (1966).	Referred to in FIFRA at §135b(d), and FD&C Act at §346a (i) (2) (3), 348(g) (2), and Special Packaging of Household Substances Act at §1474 (b) (1).
1.8	Courts of Appeals; Certiorari, Appeal; Certified Questions, as amended, 28 U.S.C. §1254 (1948).	Referred to in FIFRA at §135b(d), and FD&C Act at §§346a(i)(5), 348(g)(5), and Special Packaging of Household Substances Act at §1474(b)(5).
1.9	Adulterated Food, as amended, 21 U.S.C. §432(a) (1968).	Referred to in FD&C Act at §§346, 346a(a), 348(a((2).
1.10	Appointment and Compensation of Advisory Committee, Color Additive Amendments of 1960, as amended, 21 U.S.C. §§376(b)(5)(D) (1970).	Referred to in FD&C Act at §346a(g).
1.11	Regulations and Hearings—Authority to Promulgate Regulations, 21 U.S.C. §371 (1960).	Referred to in FD&C Act at §346a(k), and Special Packaging of Household Substances Act at §1474(a).
1.12	Penalties—Violation of §331 of this Title, 21 U.S.C. §333(c) (1970).	Referred to in FD&C Act in §346a(n).

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1.14 Rule Making, Administrative Procedure, as revised, 5 U.S.C. §553 (1966).	Special Packaging of Household Substances Act at §1474(a),(b).
1.15 Judicial Review, Relief Pending Review; Scope, as revised, 5 U.S.C. §§705, 706(2)(A),(B),(C),(D) (1966).	Special Packaging of Household Substances Act at §1474(b)(3),(4).
1.16 Per Diem, Travel and Transportation Expenses; Experts and Consultants; Individuals Serving Without Pay, as amended, 5 U.S.C. §5703 (1966).	Referred to in Special Packaging of Household Substances Act at §1475(b).

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The Regulations are noted by a three-point system (3.1, 3.2, etc.). Included in the Regulations are those not only promulgated by the Environmental Protection Agency, but those under which the Agency has direct contact.

Guidelines and reports

This subchapter is noted by a four-point system (4.1, 4.2, etc.). In this subchapter is found the statutorily required reports of EPA, published guidelines of EPA, selected reports other than EPA's and inter-departmental agreements of note.

UPDATING

Periodically, a supplement will be sent to the interagency distribution and made available through the U.S. Government Printing Office in order to provide an accurate working set of EPA Legal Compilation.

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- (1) Senate Committee on Interstate and Foreign Commerce, S. REP. No. 1592, 85th Cong., 2d Sess. (1958). 696
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- (1) Senate Committee on Interstate and Foreign Commerce, S. REP. No. 708, 86th Cong., 1st Sess. (1959). 705
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(1) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 91-1297, 91st Cong., 2d Sess. (1970). ———— 1001

(2) Senate Committee on Labor and Public Welfare, S. REP. No. 91-1090, 91st Cong., 2d Sess. (1970). ———— 1002

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(2) Senate Committee on Labor and Public Welfare, S. REP. No. 2752, 84th Cong., 2d Sess. (1956). 1061

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(2) Senate Committee on the Judiciary, S. REP. No. 2129, 85th Cong., 2d Sess. (1958). 1069

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(1) Senate Committee on Labor and Public Welfare, S. REP. No. 795, 86th Cong., 1st Sess. (1959). 1076

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(1) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 700, 82nd Cong., 1st Sess. (1951). 1095

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(c) Oct. 17: House concurs in Senate amendments, p. 13378. 1119

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(1) Senate Committee on Labor and Public Welfare, S. REP. No. 795, 86th Cong., 1st Sess. (1959). 1121

(2) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 1761, 86th Cong., 2d Sess. (1960). 1124

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(b) Vol. 106 (1960), June 25: Amended and passed House, pp. 14373, 14377;* 1133

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(1) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 130, 89th Cong., 1st Sess. (1965). 1134

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(1) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 1546, 90th Cong., 2d Sess. (1968). 1139

(2) Senate Committee on Labor and Public Welfare, S. REP. No. 1609, 90th Cong., 2d Sess. (1968). 1149

(3) Committee of Conference, H.R. REP. No. 1958, 90th Cong., 2d Sess. (1968). 1156

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(c) Oct. 11: House agrees to conference report, pp. 30761, 30762; 1165

(d) Oct. 11: Senate agrees to conference report, pp. 30963, 30965. 1167

1.13h Comprehensive Drug Abuse Prevention and Control Act, October 27, 1970, P.L. 91–513, Title II, §701(b), 84 Stat. 1281. 1170

(1) Senate Committee on the Judiciary, S. REP. No. 91–613, 91st Cong., 1st Sess. (1969). 1171

(2) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 91–1444, (Parts 1 and 2), 91st Cong., 2d Sess. (1970). 1174

(3) Committee of Conference, H.R. REP. No. 91–1603, 91st Cong., 2d Sess. (1970). 1176

(4) Congressional Record, Vol. 116 (1970):

(a) Jan. 28: Considered and passed Senate, p. 1690;* 1177

(b) Sept. 24: Considered and passed House, p. 33667;* 1177

(c) Oct. 7: Amended and passed Senate, pp. 35496–35497;* 1177

(d) Oct. 14: House agrees to conference report, p. 36655;* 1177

(e) Oct. 14: Senate agrees to conference report, p. 36885.* 1177

1.14 Research and Development Act, Contracts, as amended, 10 U.S.C. §§2353, 2354 (1956).
[Referred to in 42 U.S.C. §241(h)] 1178

1.14a Armed Forces Research and Development Act, July 16, 1952, P.L. 82–557, §§4, 5, 66 Stat. 725. 1179

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(1) House Committee on Armed Services, H.R. REP. No. 548, 82nd Cong., 1st Sess. (1951). 1181
(2) Senate Committee on Armed Services, S. REP. No. 936, 82nd Cong., 1st Sess. (1951). 1194
(3) Congressional Record:
(a) Vol. 97 (1951), Aug. 2: Passed House, pp. 9431–9433; 1204
(b) Vol. 98 (1952), July 3: Amended and passed Senate, pp. 9053–9054; 1210
(c) Vol. 98 (1952), July 4: House concurs in Senate amendments, pp. 9374–9375. 1212

1.14b Armed Forces Procurement Amendments of 1956, August 10, 1956, P.L. 84–1028, §§2353, 2354, 70A Stat. 134. 1213
(1) House Committee on the Judiciary, H.R. REP. No. 970, 84th Cong., 1st Sess. (1955). 1214
(2) Senate Committee on the Judiciary, S. REP. No. 2484, 84th Cong., 2d Sess. (1956). 1217
(3) Congressional Record:
(a) Vol. 101 (1955), Aug. 1: Amended and passed House, pp. 12718–12719; 1218
(b) Vol. 102 (1956), July 23: Amended and passed Senate, p. 13953;* 1219
(c) Vol. 102 (1956), July 25: House concurs in Senate amendment, p. 14455.* 1219

1.15 Rule Making, Administrative Procedure, as revised, 5 U.S.C. §553 (1966).
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1.15a Rule Making, June 11, 1946, P.L. 97–404, §4, 60 Stat. 238. 1220
(1) Senate Committee on the Judiciary, S. REP. No. 752, 79th Cong., 1st Sess. (1945). 1221
(2) House Committee on the Judiciary, H.R. REP. No. 1980, 79th Cong., 2d Sess. (1946). 1230
(3) Congressional Record, Vol. 92 (1946):
(a) March 12: Debated, amended and passed Senate, pp. 2151–2152, 2155, 2157, 2161–2162, 2165; 1241
(b) May 24: Debated, amended and passed House, pp. 5645, 5649; 5650–5652, 5656, 5660–5661; 1244
(c) May 27: Senate concurs in the House amendments, p. 5788.* 1248

1.15b Administrative Procedure and Rule Making, September 6, 1966, P.L. 89–554, §553, 80 Stat. 383. 1248
(1) House Committee on the Judiciary, H.R. REP. No. 901, 89th Cong., 1st Sess. (1965). 1249
(2) Senate Committee on the Judiciary, S. REP. No. 1380, 89th Cong., 2d Sess. (1966). 1251

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(3) Congressional Record:
  (a) Vol. 111 (1965), Sept. 7: Passed House, p. 22954;* 1251
  (b) Vol. 112 (1966), July 25: Amended and passed Senate, p. 17010;* 1252
  (c) Vol. 112 (1966), Aug. 11: House concurs in Senate amendments, p. 19077. 1252

1.16 Judicial Review; Relief Pending Review; Scope, as revised, 5 U.S.C. §§705, 706(2) (A), (B), (C), (D) (1966). [Referred to in 15 U.S.C. §1474(b) (3) (4)] 1252
  1.16a Judicial Interim Relief and Review of Agencies Acts, June 11, 1946, P.L. 79-404, §10(d), (e), 60 Stat. 243. 1253
    (1) Senate Committee on the Judiciary, S. REP. No. 752, 79th Cong., 1st Sess. (1945). 1255
    (2) House Committee on the Judiciary, H.R. REP. No. 1980, 79th Cong., 2d Sess. (1946). 1261
    (3) Congressional Record, Vol. 92 (1946):
      (a) March 12: Amended and passed Senate, pp. 2151, 2153, 2158, 2163, 2166; 1267
      (b) May 24: Debated, amended and passed House, pp. 5454-5457, 5660, 5666; 1270
      (c) May 27: Senate concurs in House amendments, p. 5790.* 1276
  1.16b Judicial Interim Relief and Review of Agency Amendments, September 6, 1966, P.L. 89-554, §§705, 706, 80 Stat. 393. 1276
    (1) House Committee on the Judiciary, H.R. REP. No. 901, 89th Cong., 1st Sess. (1965). 1277
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    (3) Congressional Record:
      (a) Vol. 111 (1965), Sept. 7: Passed House, p. 22954;* 1279
      (b) Vol. 112 (1966), July 25: Amended and passed Senate, pp. 17010, 17011;* 1279
      (c) Vol. 112 (1966), Aug. 11: House concurs in Senate amendments, p. 19077.* 1280

1.17 Per Diem, Travel and Transportation Expenses; Experts and Consultants; Individuals Serving Without Pay, as amended, 5 U.S.C. §5703 (1966).
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1.18 Federal Water Pollution Control Act, as amended, 33 U.S.C. §1155(1) (1), (2) (1970). 1281
  1.18a The Water Quality Improvement Act of 1970, April 3, 1970, P.L. 91-224, §105(L), 84 Stat. 111. 1281
    (1) House Committee on Public Works, H.R. REP. No. 91-127, 91st Cong., 1st Sess. (1969). 1283

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(2) Senate Committee on Public Works, S. REP. No. 91-351, 91st Cong., 1st Sess. (1969). 1284
(3) Committee of Conference, H.R. REP. No. 91-940, 91st Cong., 2d Sess. (1970). 1285
(4) Congressional Record:
(a) Vol. 115 (1969), April 16: Amended and passed House, p. 9293;* 1286
(b) Vol. 115 (1969), Oct. 7: Senate debated and amended, pp. 28923-28924, 28987-29008; 1286
(c) Vol. 115 (1969), Oct. 8: Passed Senate, p. 29099;* 1338
(d) Vol. 116 (1970), March 24: Senate agrees to conference report; 1338
(e) Vol. 116 (1970), March 25: House agrees to conference report, p. 9334.* 1338
1.18b Federal Water Pollution Control Act Amendments of 1972, October 18, 1972, P.L. 92-500, §104(1), 86 Stat. 822. 1338
(1) Senate Committee on Public Works, S. REP. No. 92-414, 92d Cong., 1st Sess. (1971). 1339
(2) House Committee on Public Works, H.R. REP. No. 92-911, 92d Cong., 2d Sess. (1972). 1344
(3) Committee of Conference, H.R. REP. 92-1465, 92d Cong., 2d Sess. (1972). 1345
(4) Congressional Record:
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(c) Vol. 118 (1972), Oct. 4: House and Senate agreed to conference report;* 1345
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3.5 FAA Certification of Private Agricultural Operations, Federal Aviation Administration, 14 C.F.R. §137.1–137.77 (1968). 1357
3.6 Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities, U.S. Environmental Protection Agency, 40 C.F.R. §180.1–180.1023 (1972). 1357
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1.2c 1940 REORGANIZATION PLAN NO. IV, §12, 54 STAT. 1237

SEC. 12. *Transfer of Food and Drug Administration.*—The Food and Drug Administration in the Department of Agriculture and its functions, except those functions relating to the administration of the Insecticide Act of 1910 and the Naval Stores Act, are transferred to the Federal Security Agency and shall be administered under the direction and supervision of the Federal Security Administrator. The Chief of the Food and Drug Administration shall hereafter be known as the Commissioner of Food and Drugs.

[p. 1237]

1.2d 1953 REORGANIZATION PLAN NO. I, §§5, 8, 67 STAT. 632

SEC. 5. *Transfers to the Department.*—All functions of the Federal Security Administrator are hereby transferred to the Secretary. All agencies of the Federal Security Agency, together with their respective functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available), and all other functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available) of the Federal Security Agency are hereby transferred to the Department.

SEC. 8. *Abolitions.*—The Federal Security Agency (exclusive of the agencies thereof transferred by section 5 of this reorganization plan), the offices of Federal Security Administrator and Assistant Federal Security Administrator created by Reorganization Plan No. I (53 Stat. 1423), the two offices of assistant heads of the Federal Security Agency created by Reorganization Plan No. 2 of 1946 (60 Stat. 1095), and the office of Commissioner for Social Security created by section 701 of the Social Security Act, as amended (64 Stat. 558), are hereby abolished. The Secretary shall make such provisions as may be necessary in order to wind up any outstanding affairs of the Agency and offices abolished by this section which are not otherwise provided for in this reorganization plan.

[p. 632]

1.2e FOOD ADDITIVES AMENDMENTS OF 1958

September 6, 1958, P.L. 85–929, §§3(c), 4, 6(a), 72 Stat. 1784

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Amendment of 1958".

SEC. 2. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end of such section the following new paragraphs:

"(s) The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

"(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, The Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

"(t) The term 'safe', as used in paragraph (s) of this section and in section 409, has reference to the health of man or animal."

SEC. 3. (a) Clause (2) of section 402 (a), as amended, of such Act is amended to read as follows: "(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409:

Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;".

[p. 1784]

(b) Section 402 (a), as amended, of such Act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: "or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409."

(c) The first sentence of section 406 (a) of such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

SEC. 4. Chapter IV of such Act is amended by adding at the end thereof the following new section:

"FOOD ADDITIVES

"Unsafe Food Additives

SEC. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

"(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

"Petition To Establish Safety

"(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

"(2) Such petition shall, in addition to any explanatory or supporting data, contain—

"(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

"(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

"(C) all relevant data bearing on the physical or other technical effects such additive is intended to produce, and the quantity of such additive required to produce such effect;

"(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

"(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

"(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, [p. 1785] without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

"(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

"(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

"Action on the Petition

"(c) (1) The Secretary shall—

"(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reason for such action; or

"(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

"(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

"(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

"(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe; *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

"(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

"(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

"(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

"(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

[p. 1786]

"(5) In determining for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

"(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

"(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

"(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

"Regulation Issued on Secretary's Initiative

"(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

"Publication and Effective Date of Orders

"(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

"Objections and Public Hearing

"(f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary, shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

"(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

"(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"Judicial Review

"(g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court [p. 1787] of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

"(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

"(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.

"(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

"(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

"Amendment or Repeal of Regulations

"(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

"Exemptions for Investigational Use

"(i) Without regard to subsection (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

SEC. 5. Section 301 (j) of such Act is amended by inserting "409," after "404,".

SEC. 6. (a) Except as provided in subsections (b) and (c) of this section, this Act shall take effect on the date of its enactment.

(b) Except as provided in subsection (c) of this section, section 3 of this Act shall take effect on the one hundred and eightieth day after the date of enactment of this Act.

(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act shall take effect—

(1) either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such additional period (but not later than two years from such effective date established in subsection (b) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the

public health and that conditions exist which necessitate the prescribing of such an additional period, or

(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act becomes effective.

whichever date first occurs.

SEC. 7. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Poultry Products Inspection Act. (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following).

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SEC. 8. The annual rate of basic compensation of the Commissioner of Food and Drugs shall be $20,000.

SEC. 9. Section 208 (g) of the Public Health Service Act, as amended (42 U. S. C. 210 (g)), is amended by striking out the phrase "in the professional and scientific service" and inserting in lieu thereof the phrase "in the professional, scientific, and executive service" and by striking out the phrase "of specially qualified scientific or professional personnel" and inserting in lieu thereof "of specially qualified scientific, professional, and administrative personnel."

Approved September 6, 1958.

[p. 1789]

1.2e (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 2284, 85th Cong., 2d Sess. (1958)

FOOD ADDITIVES AMENDMENT OF 1958

JULY 28, 1958.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WILLIAMS of Mississippi, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 13254]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, having considered the same, report favorably thereon with an amendment and recommend that the bill, as amended, do pass.

The amendment is as follows:

The amendment strikes all of the text of the introduced bill and inserts in lieu thereof a substitute which appears in the reported bill in italic type.

PURPOSE OF LEGISLATION

The purpose of the legislation is twofold:

(1) To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels.

Existing law bars the use, even at safe levels, of additives which are poisonous or deleterious unless their use is required in production or cannot be avoided by good manufacturing practice. The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food. On the other hand, present law entirely prohibits the use of these additives even if their use at [p. 1] safe levels would advance our food technology and increase and improve our food supplies.

The Food and Drug Administration has pointed out the dangers to the public health resulting from the failure of the present law to require pretesting of food additives. On the other hand that agency agrees that the present law should be changed to permit the use of additives at safe levels in order to advance our food technology.

While the responsible elements of the affected industries traditionally have voluntarily undertaken to pretest food additives they are willing to assume this responsibility under a statutory mandate. Thus, those elements of the industry which in the past have used harmful additives or additives of unknown toxicity without pretesting will in the future under this legislation be required to assume the same duties as the responsible elements have heretofore voluntarily assumed.

Although there has been complete agreement as to the need for this legislation, there have been differencs between the Food and Drug Administration and the affected industries with respect to procedures to be followed in determining the safety of an additive and the method of judicial review of such a determination. With respect to these controversial procedural questions, the committee feels the proposed legislation steers a course which satisfies both the need for protecting the public health and the legitimate interests of industry and Government in fair procedures.

HISTORY OF LEGISLATION

During the 81st Congress, a Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics (better known as the Delaney committee, named after its chairman, Congressman James J. Delaney) was created in the House of Representatives to study the need to amend the present Federal Food, Drug, and Cosmetic Act in this respect. After extended hearings, the committee on June 30, 1952, filed a report (H. Rept. No. 2356, 82d Cong., 2d sess.) urging amending the present law so that chemicals employed in or on foods would be subjected to substantially the same safety requirements as exist in the law for new drugs.

Bills to accomplish the objectives of the report were introduced by Congressman Delaney and referred to this committee during the 83d Congress and subsequent Congresses, and other Members of Congress introduced numerous bills differing from the prototype bills primarily with respect to agency procedure and judicial review.

During the 83d Congress, the committee held hearings and reported favorably related legislation providing for the pretesting of, and the establishment of safe tolerances for, pesticide chemicals. This bill was enacted into law (Public Law 518, 83d Cong.).

During the 2d session of the 84th Congress, the Subcommittee on Health and Science, under the chairmanship of the late full committee chairman, J. Percy Priest, held 5 days of hearings on 10 bills dealing with chemical additives in and on food. The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the agency and judicial review procedures to be followed in determining the safety of chemical additives. This disagreement was not resolved, and no chemical additive legislation was enacted during the 84th Congress.

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During the 85th Congress, the Subcommittee on Health and

Science held 11 days of hearings on 9 bills.[1] The hearings included 2 days of testimony by a panel of outstanding scientists and experts selected by the National Academy of Sciences at the request of the subcommittee, to give the subcommittee the scientific background with regard to the testing and evaluating of the safety of chemical additives. The subcommittee also heard witnesses from industry, labor, and consumer organizations, representatives from the Department of Health, Education, and Welfare, including those from the Food and Drug Administration, and the chief judge of the third judicial circuit appearing on behalf of the Judicial Conference of the United States.

As a result of the hearings and after consideration of the various bills, the chairman of the subcommittee, Congressman John Bell Williams of Mississippi, introduced a clean bill (H. R. 13254) which was reported unanimously by the subcommittee to the full committee.

The full committee unanimously reported the bill with one amendment which strikes out all after the enacting clause and inserts in place of the introduced bill a substitute. The principal difference between the proposed committee amendment and the introduced bill is the elimination of the provisions in the introduced bill relating to scientific advisory committees. The remaining differences are the result of clerical, technical, and clarifying changes.

PRINCIPAL PROVISIONS OF LEGISLATION

Substances covered by legislation

Pretesting is required under this legislation only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures (including a review of the existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as "intentional additives."

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."

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[1] H.R. 366 (O'Hara of Minnesota), H.R. 6747 (Harris), H.R. 7700 (Fulton), H.R. 7708 (Delaney) H.R. 7938 (Sullivan), H.R. 8390 (Harris), H.R. 8629 (Wolverton), H.R. 8112 (Miller), and H.R. 10404, (Williams of Mississippi).

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous [p. 3] and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term "food additive" as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

Regulation to establish safety

A regulation prescribing the conditions under which an additive may be safely used may be issued by the Secretary of Health, Education, and Welfare either on the basis of a petition filed by any person (ordinarily the manufacturer of the additive) or on the Secretary's own initiative.

The petition would set forth the name and all pertinent information concerning the additive, including, where available, its chemical identity and composition; full reports of scientific investigations of safety for use; the conditions of the proposed use of such additive; relevant data bearing on the physical or other technical effect such additive is intended to produce; the quantity required to produce such effect; when requested by the Secretary, the methods used to produce the additive; and a description of practical methods to determine the quantity of such additive left in or on food because of its use.

Trade secrets supplied to the Secretary would be protected under this legislation from unauthorized disclosure by departmental personnel.

The Secretary would either, by order, establish a regulation prescribing the conditions under which such additive may be safely used, or he would, by order, deny the petition and notify the petitioner of the reasons for such action. Such orders would be issued within 90 days after the date of filing of the petition unless the Secretary, by written notice to the petitioner, extends such period for not more than an additional 90 days to enable him to study the petition.

Concept of safety

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that [p. 4] it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

In determining the "safety" of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related substances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.

Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.

The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the

specific additive in question, among others, the following relevant factors: (1) the probable consumption of the additive and of any substance formed in or on food because of the use of such additive; (2) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and (3) safety factors which qualified experts consider appropriate for the use of animal experimentation data.

In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would have to consider any residues that might appear in eggs produced by the poultry. Similarly, in determining the safety of additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal.

Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count.

Grounds for denial of petition

The Secretary would deny a petition to establish the safety of an additive if the data before the Secretary fail to establish that the proposed use of the additive under the specified conditions of use will be safe.

The Secretary could also deny a petition on the ground that the proposed use of the additive would promote deception of the consumer in violation of the Food and Drug Act or would otherwise result in adulteration or in misbranding of food within the meaning of the Food and Drug Act.

Tolerance limitations

In the case of an additive which in the judgment of the Secretary based upon a fair evaluation of the data before him, requires a tolerance limitation in order to assure that the proposed use of such additive will be safe, the legislation establishes two standards:

(1) the Secretary may not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

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(2) the Secretary may not establish a regulation for such pro-

posed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

The phrase "physical or other technical effect" refers to the objective effect which the additive may have on the appearance, flavor, texture, or other aspects of a food. The question of whether an additive produces such effect (or how much of an additive is required for such effect) is a factual one, and does not involve any judgment on the part of the Secretary of whether such effect results in any added "value" to the consumer of such food or enhances the marketability from a merchandising point of view.

Advisory committees

The committee has deleted the advisory committee procedure from the bill because there does not appear to be any need for this complicated mechanism for securing the views of scientists. The Department already has the privilege of making inquiry of competent outside scientists on technical matters.

Public hearings

Any person adversely affected by an order of the Secretary may file objections thereto and request a public hearing. At such hearings the Secretary would receive evidence relevant and material to the issues raised and would by order act upon such objections.

Judicial review

The committee has given long and careful thought to the problem of the scope of judicial review under this legislation. This problem was discussed exhaustively by several witnesses, including a Federal judge who testified on behalf of the Judicial Conference of the United States.

The committee feels that the Secretary's findings of fact and orders should not be based on isolated evidence in the record, which evidence in and of itself may be considered substantial without taking account of contradictory evidence of possible equal or even greater substance.

In the course of scientific panel hearings, the subcommittee was impressed with the wide range of scientific judgment factors which are involved in determining the safety of a food additive. Considering the eminent qualifications of all the scientists and experts who participated in these panel hearings, the scientific testimony of any one of the participants must be considered "substantial evidence." Nevertheless, any conclusions based solely on the scientific judgment of any one of the participants without taking account of contradictory scientific views expressed by other participants cannot be considered conclusions based upon a fair evaluation of the entire record.

Thus, under this legislation, the Secretary's findings of fact and orders based thereon must be based upon a fair evaluation of the entire record. The committee adopted the language "fair evaluation of the entire record" because it seemed to express most clearly the standard of judicial review of administrative findings of fact and orders based thereon which the committee feels should prevail.

The bill provides that the reviewing court shall not sustain the order of the Secretary if he failed to base such order upon a fair evaluation of the entire record at such hearing, or if he failed to include in such order a statement setting forth in detail the findings [p. 6] and conclusions upon which the order is based. The court must sustain the findings of the Secretary with respect to questions of fact if based upon a fair evaluation of the entire record.

Judicial review of any order of the Secretary under this legislation may be obtained in the United States court of appeals for the circuit wherein appellant resides, or has his principal place of business, or in the United States Court of Appeals for the District of Columbia.

Effective date

This legislation will, except as hereinafter stated, take effect on the date on which it is enacted. Thus the Food and Drug Administration can immediately begin making determinations as to the safety of food additives.

However, since it will take a certain amount of time to make these determinations of safety, the provisions of section 3 of the legislation (which will have the effect of permitting seizure, injunction suits, and criminal prosecutions on account of the shipment in interstate commerce of an additive, or food containing an additive, which has not been determined to be safe) will not take effect until 180 days after the enactment of this legislation.

A further exception is made in the case of any particular commercial use of a food additive if such use began before January 1, 1958. In the case of such use, section 3 would take effect either on the establishment of an order with respect to the safety of such use, or 18 months after the date of enactment of the legislation (unless extended by the Secretary for not more than an additional 12 months), whichever date occurs first.

Meat inspection

The bill as amended provides that nothing in this legislation shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907. This provision would leave unaffected the jurisdiction of the Department of Agriculture with respect to food additives in establishments which are subject to the Meat Inspection Act.

The report of the Secretary of Health, Education, and Welfare reads as follows:

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
Washington, July 11, 1958.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: We note with gratification that the Health and Science Subcommittee of your committee has reported favorably a chemical food additives bill based essentially on H. R. 6747. We appreciate your great interest in this bill.

The subcommittee revision is acceptable to this Department.

Because of the urgent public health need for legislation requiring adequate testing of additives before they are used in food, we hope your committee can give favorable consideration to the new bill, H. R. 13254, in time for it to be acted upon by this session of Congress.

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In view of the urgency, this communication has not been submitted to the Bureau of the Budget for advice in accordance with the usual procedure on reports.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

CHANGES IN EXISTING LAW

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as introduced, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

AN ACT To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise

affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of ionizing radiation intended for any such use, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to the date of enactment of this paragraph, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use in the production, storage, or transportation of any raw agricultural commodity; or

(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

(t) The term "safe", as used in paragraph (s) of this section and in section 409, means without hazard to the health of man or animal.

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ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) *(A)* if it bears or contains any added poisonous or added deleterious substance, [except] *(except* a pesticide chemical in or on a raw agricultural [commodity,] *commodity and except food additive)* which is unsafe within the meaning of section 406, or *(B)* if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section [408 (a)] *408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a* *tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing by cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;* or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; *or (7) if it has been intentionally subjected to ionizing radiation, unless the use of the ionizing radiation was in conformity with a regulation or exemption in effect pursuant to section 409.*

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TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) *(A)* of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations[3] limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) *(A)* of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors[4] which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

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TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

SEC. 408. (a) Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 402 (a) unless—

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(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Secretary of Health, Education, and Welfare under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Secretary under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 402 (a).

(b) The Secretary shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Secretary shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture as submitted with a certification of usefulness under subsection (l) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Secretary may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Secretary does not justify the establishment of a greater tolerance.

(c) The Secretary shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

(d) (1) Any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Secretary of Health, Education, and Welfare, a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of, such economic poison, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

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(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Secretary upon request. Notice of the filing of such petition shall be published in general terms by the Secretary within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (1) with respect to the pesticide chemical named in the petition, the Secretary of Health, Education, and Welfare shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Secretary within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (1) with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Secretary of Health, Education, and Welfare within such period otherwise deems such referral necessary, the Secretary of Health, Education, and Welfare shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal in the petition to the Secretary, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

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(B) exempting the pesticide chemical from the necessity of tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e), may file objections thereto with the Secretary, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7 (c) of the Administrative Procedure Act (5 U.S.C., sec 1006 (c)). The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(e) The Secretary may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Secretary may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Secretary shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data [p. 19] before it, certify to the Secretary a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

(f) All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying out of their official duties under this section.

(g) Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Secretary otherwise deems such referral necessary, the Secretary shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations, thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(h) A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provisions of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal.

(i) (1) In a case of actual controversy as to the validity of any order under subsection (d) (5), (e), or (l) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia [p. 20] Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d) (5) or (e), a copy of the petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial

evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (l), a copy of the petition shall be forthwith served upon the Secretary of Agriculture, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The courts shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(j) The Secretary may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Secretary shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

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(k) Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 406 (a) upon the basis of public hearings instituted before January 1, 1953, in accordance with section 701 (e), shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m).

(l) The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d) (1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such economic poison, shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Secretary deems it necessary to postpone action for such period, on the basis of data before him, either—

(1) certify to the Secretary of Health, Education, and Welfare that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture to certify to the Secretary of Health, Education, and Welfare on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Secretary may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Secretary shall by order make the certification as proposed with respect to such parts thereof as are requested. In the event a hearing is requested, the Secretary of Agriculture shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days. The Secretary shall submit to the Secretary of Health, Education, and Welfare with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

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(m) The Secretary of Health, Education, and Welfare shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

(n) The provisions of section 303 (c) of the Federal Food, Drug, and Cosmetic Act with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

(o) The Secretary of Health, Education, and Welfare shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) The acceptance of filing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d) (5); or (5) the certification and filing in court of a transcript of the proceedings and the record

under subsection (i) (2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection.

FOOD ADDITIVES

Unsafe Food Additives

Sec. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (j) of this section or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

Petition To Establish Safety

(b) (1)Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

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(2) Such petition shall, in addition to stating reasonable grounds in support of the petition, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a full description of the methods used in, and the facilities and controls used for, the production of such additive;

(E) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(F) full reports of investigations made with respect to the toxicity or other potentiality for harm of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(4) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

Action on the Petition

(c) (1) The Secretary shall, in the absence of a referral, or request for referral, to an advisory committee made pursuant to subsection (e) of this section—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to) specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use, and shall notify the petitioner of such order; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

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(3) No such regulation shall issue if the data before the Secretary—

(A) fail to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe; or

(B) show that the proposed use of the additive would promote deception of the consumer or would be otherwise contrary to this Act.

(4) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds that the data before him do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) appropriate safety factors for the use of animal experimentation data.

Regulation Issued on Secretary's Initiative

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal, unless within such thirty-day period a person files a petition under subsection (b) with respect to such additive and requests that the proposal, or any question of fact raised thereby, be referred to an advisory committee appointed pursuant to subsection (e) of this section.

Reference to Advisory Committee

(e) (1) At any time before, or within thirty days after, publication of an order issued under subsection (c) or (d) of this section,

the petitioner may request that the petition or order thereon, or the Secretary's proposal, or any question raised by such petition, order, or proposal, be referred to an advisory committee. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee of competent experts to review the petition, order, or proposal, or question, as the case may be, and to make a report and recommendation thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition, order, proposal, or question, as the case may be, and of adequately diversified professional background selected by the National Academy of Sciences, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. [p. 25] *The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee. The Secretary shall refer the petition, order, or proposal, or question, as the case may be, to the advisory committee so appointed, and furnish such committee all the data before him. A person who has filed a petition or who has requested the referral of an order, proposal, or question, to an advisory committee, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it.*

"(2) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data,

and statement, and to any prior order issued by him in connection with such matter, the Secretary shall confirm or modify any order theretofore issued or, if no such order has been issued, shall by order establish a regulation prescribing, with respect to any particular use of the food additive involved, the conditions under which such additive may be safely used or shall, by order, deny the petition.

(3) The Secretary may by regulation condition referrals to advisory committees pursuant to this subsection upon the payment, by the person requesting the referral, of fees to defray the costs arising by reason of such referrals. Such fees, including advance deposits to cover such fees, shall be available, until expended, for paying (directly or by way of reimbursement of the applicable appropriation) the expenses of advisory committees under this subsection and other expenses arising by reason of referrals to such committees, and for refunds of excess payments.

Publication and Effective Date of Orders

(f) Any order, including any regulation established by such order, issued under subsection (c), (d), or (e) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, the order or any question related thereto is referred to an advisory committee pursuant to subsection (e) or if a hearing is sought with respect to such order pursuant to subsection (g).

Objections and Public Hearing

(g) (1) Within thirty days after publication of an order made pursuant to subsection (c), (d), or (e) of this section, any person adversely affected by such an order may file objections thereto [p. 26] *with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing if relevant and material, subject to the provisions of section 7 (c) of the Administrative Procedure Act (5 U.S.C., sec. 1006 (c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the peti-*

tioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, execpt that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Judicial Review

(h) (1) In a case of actual controversy as to the validity of any order issued under subsection (g), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith served upon the Secretary or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing, including any report, recommendation, underlying data, and reasons certified to the Secretary by an advisory committee.

(3) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were rea-

sonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts [p. 27] *and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.*

(4) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(5) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (g) (2) of this section.

Amendment or Repeal of Regulations

(i) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations, including the appointment of advisory committees and the procedure for referring matters to such committees.

Exemptions for Investigational Use

(j) Without regard to subsection (b) to (i), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

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1.2e (2) Senate Committee on Labor and Public Welfare, S. REP. No. 2422, 85th Cong., 2d Sess. (1958)

FOOD ADDITIVES AMENDMENT OF 1958

AUGUST 18 (legislative day, AUGUST 16), 1958.—Ordered to be printed

Mr. HILL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H. R. 13254]

The Committee on Labor and Public Welfare, to whom was referred the bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, having considered the same, report favorably thereon, with amendments, and recommended that the bill do pass.

EXPLANATION

The two amendments which this committee has added to the bill as passed by the House, which are discussed in detail below, do not in any way change the substance or content of the bill which passed the House of Representatives without dissent. They deal, not with the content of that bill, but with related problems regarding the ability of the Department of Health, Education, and Welfare to secure and retain the services of individuals unquestionably qualified to protect and to better the health of our people.

In explanation of the bill sent us by the House, passage of which your committee recommends with additions but without change in any of its provisions, we would point out first that under existing law the Federal Government is unable to prevent the use in foods of a poisonous or deleterious substance until it first proves that the additive is poisonous or deleterious. To establish this proof through experimentation with generations of mice or other animals may require 2 years or even more on the part of the relatively few scientists the Food and Drug Administration is able to assign to a particular problem. Yet, until that proof is forthcoming, an unscrupulous processor of foodstuffs is perfectly free to purvey to millions of our people foodstuffs containing additives which may or may not be capable of producing illness, debility, or death.

[p. 1]

Your committee is pleased to report to the Congress that an analysis of the hearings on this and related measures which have

been held over a period of some 6 years shows clearly that an overwhelming percentage of our food processors—and by this we mean the processors of well over 95 percent of the foodstuffs Americans eat—have voluntarily undertaken, at considerable expense to themselves, to thoroughly test and prove safe to humans any additives they have considered adding to foods to make them more appetizing, better keeping, more palatable, or otherwise improved. Nonetheless, existing law permits any processor who chooses to pay no heed either to the public's health or to his continuance in one particular line of business to unfairly compete with responsible processors, to defy the Food and Drug Administration and to endanger the health of millions by using an untested additive for as long a time as it may take for the Government to suspect the deleteriousness of his additives, schedule research into its properties and effects, and, finally—perhaps years later—to begin the years-long experiments needed to prove the particular additive safe or unsafe. This huge loophole is 1 of 2 flaws in existing law which, through this measure, we are attempting to fill. This bill, if enacted, will require the processor who wants to add a new and unproven additive to accept the responsibility now voluntarily borne by all responsible food processors of first proving it to be safe for ingestion by human beings.

The second flaw in existing law which has proved detrimental to consumers, to processors, and to our national economy and which this bill seeks to remove is a provision which has inadvertently served to unnecessarily proscribe the use of additives that could enable the housewife to safely keep food longer, the processor to make it more tasteful and appetizing, and the Nation to make use of advances in technology calculated to increase and improve our food supplies. Your committee agrees with the Food and Drug Administration that existing law should be changed to permit the use of such additives as our technological scientists may produce and which may benefit our people and our economy when the proposed usages of such additives are in amounts accepted by the Food and Drug Administration as safe. The rulings of the Department of Health, Education, and Welfare on such questions are, of course, subject to judicial review. The concept of safety used throughout this bill centers on the question of whether a substance is safe for use with reference to the health of man or animal. As the report of the Committee on Interstate and Foreign Commerce of the House of Representatives states, "Safety requires proof of reasonable certainty that no harm will result from the proposed use of an additive." Conscious of the fact that any substance or, for that matter, any particular food known to be good for the health of human beings can be deleterious to the health of an individual who insists on consuming inordinate amounts of it, the committee agrees with the Food and Drug Administration that, instead of insisting on proof beyond any possible doubt that no harm will result under any conceivable circumstances from the use of a particular additive—which could, of course, occur if an individual decided to eat a pound of salt or drink 4 gallons of pure water in an hour—the test which should determine whether or not a particular additive may be used in a specific percentage of relationship to the volume of the product to which it might be added should be that of reasonable certainty [p. 2] in the minds of competent scientists that the additive is not harmful to man or animal, subject to the procedural safeguards provided in the bill which assure the right to hearing and judicial review.

The bill, the passage of which your committee recommends, would correct both of these flaws in existing law. It would put upon the processor rather than our Government the burden of proving that a newly discovered substance which a processor of foodstuffs proposes to add to the food we eat is safe. It would make possible the use of additives discovered by our scientists which, having been adjudged safe for humans and animals when used in or within certain quantitative limits, could materially advance our ability to make more wholesome foods available to more people at all seasons and, perhaps, we hope, to assure to ourselves and others the ability to stockpile supplies of healthful and appetizing foods over such long periods of time as emergencies might make either desirable or essential.

HISTORY OF LEGISLATION

This bill, the passage of which your committee recommends as urgent, is the product of some 6 years of the most extensive and intensive hearings on legislative proposals in a particular field of which we have knowledge. To us it represents the workings of a free society at its best. Through public hearings, carried on over a period of 6 years, not only in every one of those 6 years but in every part of the country as well, the Committee on Interstate and Foreign Commerce of the House of Representatives was able to effect a meeting of minds and to send us a bill which has the support not only of those required by law to protect the Nation's health—the officials of the Food and Drug Administration — but also of the overwhelming majority of all those engaged in processing and selling the foodstuffs essential to the Nation's health.

Passage of this bill is strong recommended not only by the executive branch of our Government but by each of the organizations connected with the processing and distribution of foods listed below:

National Canners Association
National Dairy Products Corp., Kraft Foods division
Grocery Manufacturers of America
Millers National Federation
American Bakers Association
Manufacturing Chemists Association
Dairy Industry Committee, speaking for—
  The American Butter Institute
  The American Dairy Milk Institute
  The Evaporated Milk Association
  The International Association of Ice Cream Manufacturers
  The Milk Industry Foundation
  The National Cheese Institute
  The National Creameries Association

During the 81st Congress, a Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics (better known as the Delaney committee, named after its chairman, Congressman James J. Delaney) was created in the House of Representatives to study the need to amend the present Federal Food, Drug, and Cosmetic Act [p. 3] in this respect. After extended hearings, the committee on June 30, 1952, filed a report (H. Rept. No. 2356, 82d Cong., 2d sess.) urging amending the present law so that chemicals employed in or on foods would be subjected to substantially the same safety requirements as exist in the law for new drugs.

Bills to accomplish the objectives of that report were introduced by Congressman Delaney and referred to that committee during the 83d Congress and subsequent Congresses, and other Members of Congress introduced numerous bills differing from the prototype bills primarily with respect to agency procedure and judicial review.

During the 83d Congress, that committee held hearings and reported favorably related legislation providing for the pretesting of, and the establishment of safe tolerances for, pesticide chemicals. This bill was enacted into law (Public Law 518, 83rd Cong.).

During the 2nd session of the 84th Congress, the Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce of the House of Representatives, under the chairmanship of the late full committee chairman, J. Percy Priest, held 5 days of hearings on 10 bills dealing with chemical additives in and on food. The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the agency and judicial review procedures to be followed in determining the safety of chemical additives. This agreement was not resolved, and no chemical additive legislation was enacted during the 84th Congress.

During the 85th Congress, that subcommittee held 11 days of hearings on 9 related bills. The hearings included 2 days of testimony by a panel of outstanding scientists and experts selected by the National Academy of Sciences at the request of the subcommittee, to give the subcommittee scientific background with regard to the testing and evaluating of chemical additives. The subcommittee also heard witnesses from industry, labor, and consumer organizations, representatives from the Department of Health, Education, and Welfare, including those from the Food and Drug Administration, and the chief judge of the third judicial circuit appearing on behalf of the Judicial Conference of the United States.

As a result of those hearings and after consideration of the many related bills on this subject before the subcommittee, its chairman, Congressman John Bell Williams of Mississippi, introduced a clean bill (H. R. 13254) which was reported unanimously by the subcommittee to the full Committee on Interstate and Foreign Commerce of the House of Representatives. That bill with 1 minor committee amendment which we shall discuss below passed the House without dissent and with the 2 amendments added by your committee is the bill now under consideration.

PRINCIPAL PROVISIONS OF LEGISLATION

Substances covered by legislation

Pretesting is required under this legislation only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures (includ- [p. 4] ing a review of the existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as "intentional additives."

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term "food additive" as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment of the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

Regulation to establish safety

A regulation prescribing the conditions under which an additive may be safely used may be issued by the Secretary of Health, Education, and Welfare either on the basis of a petition filed by any person (ordinarily the manufacturer of the additive) or on the Secretary's own initiative.

The petition would set forth the name and all pertinent information concerning the additive, including, where available, its chemical identity and composition; full reports of scientific investigations of safety for use; the conditions of the proposed use of such additive; all relevant data bearing on the physical or other technical effect such additive is intended to produce; the quantity required to produce such effect; when requested by the Secretary, the methods used to produce the additive; and a description of practicable methods to determine the quantity of such additive left in or on [p. 5] food because of its use.

In addition, upon request of the Secretary, the petitioner would be required to furnish (or, if he is not the manufacturer of the additive, to have the manufacturer furnish) to the Secretary a full description of the methods, facilities, and controls used for the production of the additive. Samples of the additive or its components, or of the food in which it is to be used, would also have to be furnished if requested by the Secretary.

Trade secrets supplied to the Secretary would be protected under this legislation from unauthorized disclosure by departmental personnel.

The Secretary would either, by order, establish a regulation prescribing the conditions under which such additive may be safely used, or he would, by order, deny the petition and notify the petitioner of the reasons for such action. Such orders would be issued within 90 days after the date of filing of the petition unless the Secretary, by written notice to the petitioner, extends such period for not more than an additional 90 days to enable him to study the petition.

Concept of safety

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not— and cannot— require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

In determining the "safety" of an additive, scientists must take into consideration the cumulative effect of such additives in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related substances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.

Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.

The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the specific additive in question, among others, the following relevant factors: (1) the probable consumption of the additive and of any substance formed in or on food because of the use of such additive; (2) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and (3) safety factors which qualified experts consider appropriate for the use of animal experimentation data.

In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would have to consider any residues that might appear in [p. 6] eggs produced by the poultry. Similarly, in determining the safety of additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal.

Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count.

Grounds for denial of petition

The Secretary would deny a petition to establish the safety of an additive if the data before the Secretary fail to establish that the proposed use of the additive under the specified conditions of use will be safe.

The Secretary could also deny a petition on the ground that the proposed use of the additive would promote deception of the consumer in violation of the Federal Food, Drug, and Cosmetic Act or would otherwise result in adulteration or in misbranding of food within the meaning of the Food and Drug Act.

Tolerance limitations

In the case of an additive which, in the judgment of the Secretary based upon a fair evaluation of the data before him, requires a tolerance limitation in order to assure that the proposed use of such additive will be safe, the legislation establishes two standards:

(1) The Secretary may not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(2) The Secretary may not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

The phrase "physical or other technical effect" refers to the objective effect which the additive may have on the appearance, flavor, texture, or other aspects of a food. The question of whether an additive produces such effect (or how much of an additive is required for such effect) is a factual one, and does not involve any judgment on the part of the Secretary of whether such effect results in any added "value" to the consumer of such food or enhances the marketability from a merchandising point of view.

Public hearings

Any person adversely affected by an order of the Secretary may file objections thereto and request a public hearing. At such hearings the Secretary would receive evidence relevant and material to the issues raised and would by order act upon such objections.

Judicial review

The problem of the scope of judicial review under this legislation is an important one. It was discussed exhaustively by several witnesses before the House subcommittee, including a Federal judge who testified on behalf of the Judicial Conference of the United States.

Your committee agrees with the House that the Secretary's findings of fact and orders should not be based on isolated evidence in the record, which evidence in and of itself may be considered substantial without taking account of contradictory evidence of possibly equal or even greater substance.

[p. 7]

Following the appearance before it of a panel of outstanding scientists, the House subcommittee expressed itself as impressed with the wide range of scientific judgment factors which are involved in determining the safety of a food additive. Considering the eminent qualifications of all the scientists and experts who participated in these panel hearings, the scientific testimony of any one of the participants must be considered "substantial evidence."

Nevertheless, any conclusions based solely on the scientific judgment of any one of the participants without taking account of contradictory scientific views expressed by other participants cannot be considered conclusions based upon a fair evaluation of the entire record.

Thus, under this legislation, the Secretary's findings of fact and orders based thereon must be based upon a fair evaluation of the entire record. The committee adopted the language "fair evaluation of the entire record" because it seemed to express most clearly the standard of judicial review of administrative findings of fact and orders based thereon which the committee feels should prevail.

The bill provides that the reviewing court shall not sustain the order of the Secretary if he failed to base such order upon a fair evaluation of the entire record at such hearing, or if he failed to include in such order a statement setting forth in detail the findings and conclusions upon which the order is based. The court must sustain the findings of the Secretary with respect to questions of fact if based upon a fair evaluation of the entire record.

Judicial review of any order of the Secretary under this legislation may be obtained in the United States court of appeals for the circuit wherein appellant resides, or has his principal place of business, or in the United States Court of Appeals for the District of Columbia.

As the House committee's report makes clear, the specific language of this bill—"fair evaluation of the entire record" — represents a new standard of judicial review, which differs from the standard of "substantial evidence on the record as a whole" that has heretofore been the criterion. The chairman of the House subcommittee that drafted and reported the bill, Hon. John Bell Williams, used the following words in explaining to the House this significant change in existing law:

> Ever since the Congress began delegating regulatory functions to administrative agencies of the Government there has been disagreement among lawyers as to the fairness of the procedures under which the agencies operate. In 1946, the Administrative Procedure Act was passed in an effort to formalize the day-to-day rulemaking and regulatory procedures of Government agencies. The 1946 act provides that unless the findings of fact upon which administrative orders are based are supported by "substantial evidence" a Federal court of appeals can reverse the order of the administrative agency. Court decisions have required that an administrative agency

must give consideration to the entire record, including contradictory evidence, when it determines facts.

Manufacturers of food and of food additives have manifested concern that under an administrative type of control over the use of food additives, such as is provided by H. R. 13254, it would be possible for the institutional decisions of [p. 8] the Secretary of Health, Education, and Welfare to be based, for example, more upon the personal convictions of scientists employed by the Food and Drug Administration regarding the safety of an additive than upon the inferences fairly to be drawn from the scientific evidence of record. H. R. 13254 provides that orders regarding the use of food additives must "be based upon a fair evaluation of the entire record." The committee has endeavored to prescribe a new statutory criterion requiring that a high standard of fairness be observed in administrative rulemaking under this bill. Personal attitudes or preferences of administrative officials could not prevail on the basis of being supported by substantial evidence picked from the record without regard to other evidence of probative value in the record. The United States Courts of Appeals will be able to enforce this high standard by determining whether the Secretary of Health, Education, and Welfare has given appropriate consideration to the inferences which should fairly be drawn from all of the evidence of record.

Effective date

This legislation will, except as hereinafter stated, take effect on the date on which it is enacted. Thus the Food and Drug Administration can immediately begin making determinations as to the safety of food additives.

However, since it will take a certain amount of time to make these determinations of safety, the provisions of section 3 of the legislation (which will have the effect of permitting seizure, injunction suits, and criminal prosecutions on account of the shipment in interstate commerce of an additive, or food containing an additive, which has not been determined to be safe) will not take effect until 180 days after the enactment of this legislation.

A further exception is made in the case of any particular commercial use of a food additive if such use began before January 1, 1958. In the case of such use, section 3 would take effect either on the establishment of an order with respect to the safety of such use, or 18 months after the date of enactment of the legislation (unless extended by the Secretary for not more than an additional 12 months), whichever date occurs first.

Meat inspection

The bill as amended provides that nothing in this legislation shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907. This provision would leave unaffected the jurisdiction of the Department of Agriculture with respect to the use of food additives in meat or meat food products in establishments which are subject to the Meat Inspection Act.

DEPARTMENTAL REPORT

The report of the Secretary of Health, Education, and Welfare on S. 4193, sponsored by Senator Hill and Senator Smith of New Jersey, which is identical, save for the nonsubstantive amendments added by your committee and one amendment accepted by [p. 9] the committee on the House of Representatives and discussed below, is as follows:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
July 29, 1958.

Hon. LISTER HILL,
Chairman, Committee on Labor and Public Welfare,
United States Senate, Washington, D. C.

DEAR MR. CHAIRMAN: This is in response to your request for a report on S. 4193, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

S. 4193 is in substantial agreement with S. 1895 which was drafted in this Department and submitted to the President of the Senate with our letter of April 5, 1957 (copy enclosed). The discussion of the principal features of the draft bill, which accompanied our letter of April 5, would apply in general to S. 4193.

We understand that S. 4193 is identical with H. R. 13254, the bill drafted by the House Committee on Interstate and Foreign Commerce after it held extensive hearings on food additives legislation. In our letter of July 11, 1958, to the chairman of the House Committee on Interstate and Foreign Commerce, we endorsed H. R. 13254 and it has now been reported favorably by the House committee.

S. 4193 would accomplish the public health benefits that we envisioned in drafting proposed legislation last year. We urgently recommend its enactment or the enactment of H. R. 13254 at this session of Congress.

In view of the urgency, time has not permitted the submission of this report to the Bureau of the Budget in accordance with the usual procedure.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary.

AMENDMENTS

Two amendments made by your committee to the bill as passed by the House are explained below. We would like, in addition, to call attention to the fact that the Committee on Interstate and Foreign Commerce of the House of Representatives, before bringing the bill to a vote in the House, decided to add to its previously approved bill the provision which appears on page 8 of the House-passed bill (lines 10 to 15) and reads as follows:

> *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal;

Your committee, which has the responsibility in the Senate of considering all legislation primarily relating to the health of our people, is well aware and thoroughly approving of the vast amount of time and energy which Congressman Delaney, author of that amendment, has devoted to the fight against cancer and to our attempts to find its cause and cure. We have no objections to that amendment whatsoever, but we would point out that in our opinion [p. 10] it is the intent and purpose of this bill, even without that amendment, to assure our people that nothing shall be added to the foods they eat which can reasonably be expected to produce any type of illness in humans or animals. We applaud Congressman Delaney for having taken this, as he has every other opportunity, to focus our attention on the cancer-producing potentialities of various substances, but we want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability. In short, we believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration.

The first of the amendments added to the bill by your committee appears on page 15 as section 8 of the bill. It would increase the salary of the Commissioner of Food and Drugs from $17,500 to $20,000. In recommending this increase, the Department of Health, Education, and Welfare set forth its reasoning in a memorandum to the committee which we set forth herewith.

July 24, 1958.

MEMORANDUM TO THE COMMITTEE ON LABOR AND PUBLIC WELFARE, UNITED STATES SENATE

SALARY OF THE COMMISSIONER OF FOOD AND DRUGS

The position of Commissioner of Food and Drugs is currently classified as GS-18, which carries a salary of $17,500. In the light of the scope and complexity of the program administered by the Commissioner of Food and Drugs the Department of Health, Education, and Welfare believes that his salary should be increased to $20,000.

The importance of such an increase in the salary of the Commissioner of Food and Drugs has now been accentuated by the provision of the recent Classified Pay Act under which five much-needed scientific supergrade positions have been assigned to the Food and Drug Administration. Two of these positions will carry salaries higher than the current salary of the Commissioner; three will carry the same salary.

Statutory language to provide for the proposed increase is attached.

ELLIOT L. RICHARDSON,
Assistant Secretary.

Your committee not only agrees with the Department but also believes the recommended action to be long overdue. We unanimously recommend its approval.

The second amendment adopted by the committee has to do with key personnel attached to the National Institutes of Health. It appears as section 9 on page 15 of the bill. It does not change the maximum salary limitations under that section of the act it amends, nor does it increase the total number of supergrade positions allocated by the Congress to the National Institutes of Health. It merely clarifies the intent of the Congress that, just as in the case of the recently enacted National Aeronautics and Space Act in which that intent was explicitly set forth, so too in the case of the National Institutes of Health do we intend to permit the [p. 11] employment in these key positions of men with superior executive and administrative skills as well as men with superior scientific and professional skills.

CHEMICAL PRESERVATIVES

During the committee's deliberations on this measure, Senator Goldwater questioned Commissioner Larrick of the Food and Drug Administration concerning the Department's policies and regulations with respect to preservatives which might be added to cantaloups and other produce of the soil after harvesting. While those questions are the subject of other legislation already on the statute books and do not relate to the measure before us, the committee believes that the explanation given by Commissioner Larrick concerning current law, policies, and regulations bearing on that problem may well be of interest to individuals concerned with any aspect of legislation dealing with the safety of foodstuffs. Therefore, and in response to Senator Goldwater's request, the committee is happy to include in this report that confirmatory letter sent by Commissioner Larrick to the chairman of this committee which sums up the Commissioner's replies to Senator Goldwater's questions. It is as follows:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
August 15, 1958.

Hon. LISTER HILL,
Chairman, Committee on Labor and Public Welfare,
United States Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This confirms the statement I made today before the Committee on Labor and Public Welfare in response to questions by Senator Goldwater about the required declaration of the presence and the names of chemical preservatives on cantaloups and other produce of the soil.

Cantaloups and other produce of the soil are not required to have a sticker label on them for this purpose. If they are treated with a pesticide chemical after harvest to prevent deterioration, it is enough that the shipping container has a label giving this information. If the cantaloups are taken away from the containers for retail sales display, all we require is that there be a counter card containing the information. Each melon need not be marked.

Pesticide chemicals applied before harvest are used under spray schedules and other safeguards developed by the Department of Agriculture and disseminated by the county agents, and by labeling on the pesticides themselves. Since the packing-shed operator ordinarily has no means of knowing what pesticides may have been used in growing all the fruit he buys, we have issued an exempting regulation recognizing that it is impractical for him to label fruit with information as to the preharvest treatment. We could not extend this exemption to postharvest treatments because we could not make the statutory finding that the label declaration was impractical.

We have recognized that it may be impractical in the retail store to name on the counter card the pesticides on citrus fruit, and have proposed a regulation to require that the counter card have only the information that a preservative has been used, but not the name of the preservative.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[p. 12]

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

AN ACT To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

* * * * * * *

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

> ***"(1) a pesticide chemical in or on a raw agricultural commodity; or***
>
> ***(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or***
>
> ***(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following)";***

(t) The term "safe", as used in paragraph (s) of this section and in section 409, has reference to the health of man or animal.

[p. 13]

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

* * * * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, *409*, 505, 506, 507, or 704 concerning any method or process which as a trade secret is entitled to protection.

* * * * * * *

CHAPTER IV—FOOD

* * * * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) *(A)* if it bears or contains any added poisonous or added deleterious substance, [except] *(except* a pesticide chemical in or on a raw agricultural [commodity,] *commodity and except a food additive)* which is unsafe within the meaning of section 406, or *(B)* if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section [408 (a)] *408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;* or (3) if it con-

sists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; *or (7) if it has been intentionally subjected to radiation, unless the use* [p. 14] *of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.*

* * * * * * *

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) *(A)* of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) *(A)* of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

* * * * * * *

Food Additives

Unsafe Food Additives

SEC. *409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe* *for the purposes of the application of clause (2) (C) of section 402 (a), unless—*

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

Petition to Establish Safety

(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

[p. 15]

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the meth-

ods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

Action on the Petition

(c) (1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

[p. 16]

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

Regulation Issued on Secretary's Initiative

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

Publication and Effective Date of Orders

(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hear-

ing is sought with respect to such order pursuant to subsection (f).

[p. 17]

Objections and Public Hearing

(f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair valuation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Judicial Review

(g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any persons who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire

record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

[p. 18]

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

Amendment or Repeal of Regulations

(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

Exemptions for Investigational Use

(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

PUBLIC HEALTH SERVICE ACT, AS AMENDED (42 U.S.C. 310 (g))

* * * * * * *

SEC. 208.

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(g) The Secretary is authorized to establish and fix the compensation for, within the Public Health Service, not more than eighty-five positions of which not less than seventy-three shall be for the National Institutes of Health in the professional, [and] scientific, *and executive* service, each such position being established to effectuate those research and development activities of the Public Health Service which require the services of specially qualified scientific, [or] professional, *and administrative* personnel: *Provided,* That the rates of compensation for positions established pursuant to the provisions of this subsection shall not be less than $12,500 per annum nor more than $19,000 per annum, and shall be subject to the approval of the Civil Service Commission. Positions created pursuant to this subsection shall be included in the classified civil service of the United States but appointment to such positions shall be made without competitive examination upon approval of the proposed appointee's qualification by the Civil Service Commission or such officers and agents as it may designate for this purpose.

[p. 19]

1.2e (3) CONGRESSIONAL RECORD, VOL. 104 (1958)

1.2e (3) (a) Aug. 23: Amended and passed Senate, pp. 19358–19359

[No Relevant Discussion on Pertinent Section]

1.2e (3) (b) Aug. 23: House concurs in Senate amendments, p. 19641

[No Relevant Discussion on Pertinent Section]

1.2f. COLOR ADDITIVES AMENDMENTS OF 1960

July 12, 1960, P.L. 86–618, Title I, Section 103(a) (1), 74 Stat. 398

REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

Sec. 103 (a) Such Act is further amended by—

(1) repealing subsection (b) of section 406 and striking out the subsection designation "(a)" after "SEC. 406." in such section:

[p. 398]

1.2f (1) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 795, 86th Cong., 1st Sess. (1959)

COLOR ADDITIVE AMENDMENTS OF 1959

AUGUST 21, 1959.—Ordered to be printed

Mr. HILL, from the committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany S. 2197]

The Committee on Labor and Public Welfare, to whom was referred the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

EXPLANATION

S. 2197 is designed to better protect the public health with respect to procedures necessary to assure the safety of color additives in foods, drugs, and cosmetics and to authorize the use of such color additives as have been predetermined to be perfectly safe in the amounts in which they are to be used. The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act with a scientifically sound and uniform system for the listing of color additives of any kind which may be safely used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

Under existing law coal-tar colors may not be used in foods, drugs, or cosmetics unless they have been certified by the Food and Drug Administration as harmless and suitable for use. A recent Supreme Court decision has defined the "harmless" principle as

meaning harmless regardless of the quantity of the coal-tar color which is being used. Thus, a color must be decertified if any quan-
[p. 1]
tity or concentration of the color is harmful, even though in lesser concentrations it may be perfectly safe. Because of this principle, as defined by the Supreme Court, it has been necessary for the Food and Drug Administration to withdraw certification of seven food colors. Seventeen additional colors have been proposed for delisting. The effect of the application of the "harmless" principle in terms of existing law is to cause many of the coal-tar colors widely used in industry to be no longer available, and the number of colors withdrawn will eventually seriously handicap manufacturers of foods, drugs, and cosmetics in the production of products in the manner that is customary and usual.

Many food industries find themselves seriously affected by the delisting of colors. If additional proposed delistings are accomplished, similar effect is faced by drug and cosmetic industries. The very existence of many products depends upon the use of suitable color.

This legislation is necessary, because it will give the Secretary of Health, Education, and Welfare a flexibility, which he does not have under the present law, to certify coal-tar colors within tolerance limits which he determines are safe.

Two amendments to the bill as originally introduced were adopted by the committee. Both amendments were developed cooperatively by the committee staff, representatives of the industries concerned, and representatives of the Food and Drug Administration. Both have been declared acceptable by the Administration and by industry. Their objectives are, first, to permit those additives found "safe" by the Secretary under the procedures set forth in the Food Additives Amendments Act of 1958 to be considered "safe" when used as color additives, and secondly, to relieve the Administration from the obligation of requiring the use of certain analytical methods, when, in its opinion, they are not needed.

The bill as amended has the endorsement of the Administration and of the following business groups which have concerned themselves with the legislation: The Certified Color Industry Committee, the Toilet Goods Association, the National Association of Margarine Manufacturers, the International Association of Ice Cream Manufacturers, the Grocery Manufacturers of America, and the National Confectioners Association.

S. 2197 was introduced at the request of the Department of

Health, Education, and Welfare with the approval of the Bureau of the Budget.

DEPARTMENTAL COMMENT

Set forth below are, first, the letter of transmittal from Arthur S. Flemming, Secretary, Department of Health, Education, and Welfare, requesting the introduction of the legislation and setting forth the principal reasons which give rise to the need for immediate action in this field, and, second, letters dated August 7 and August 12, 1959, from Elliot L. Richardson, Assistant Secretary, Department of Health, Education, and Welfare, expressing approval of the committee amendments.

[p. 2]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., May 29, 1959

HON. RICHARD M. NIXON,
President of the Senate,
Washington, D.C.

DEAR MR. PRESIDENT: We are enclosing herewith a draft bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on food, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used. The bill may be referred to by the short title "Color Additive Amendments of 1959."

We respectfully urge the prompt consideration and enactment of this bill by Congress.

The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act, with a scientifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

The principal reasons which give rise to the need for this legislation may be summarized as follows:

1. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection, in that it does not allow us to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, we must ban the use of such a color completely as not being "harmless," if it is found to be toxic in the laboratory when fed in some concentrations, even though its actual level and manner of use may be completely safe; for externally applied drugs and cosmetics the same principle applies if toxicity appears in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use is wholly safe.

The principle of allowing colors to be used under tolerance limitations was endorsed in 1956 by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program of the Food and Drug Administration, as indicated by the following excerpt from the committee's report: "This committee feels compelled to indicate that certification of a compound as 'harmless and suitable for use' in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified."

2. The theoretically "perfect" public-health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While, theoretically, only "harmless" colors may be listed, [p. 3] a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many, perhaps most, of the so-called colors on the list may in fact be toxic in some concentrations; yet we cannot take a particular color off the list until we establish its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the established colors would have to be completed—primarily by industry—and during which we could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

3. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present there are no provisions for the certification of non-coal-tar colors; there is, moreover, no pretesting requirement for non-coal-tar color additives as such, other than food additives.

4. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress in temporary emergency legislation (Public Law 86–2) with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring oranges, after previous adoption of the safe-for-use principle in the Food Additives Amendment of 1958 (Public Law 85–929). The only reason we had suggested to Congress that the emergency legislation for citrus red No. 2 have a termination date was that color legislation limited to particular colors and articles of food is discriminatory and that permanent legislation on this subject should contain additional safeguards. Moreover, Public Law 86–2 on its face indicates the expectation that Congress will before long address itself to the problem of general color legislation.

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

A more detailed explanation of the principal changes made in existing law, and the reasons therefor, is attached to the draft bill. There is also enclosed herewith a section-by-section analysis of the bill.

[p. 4]

The establishment of a tolerance system in this field requires, to an extent not involved in a system without tolerance limitations, a program of education of the user industries and public, and a program of enforcement activities by a thoroughly trained corps of inspectors and analysts. The fee provisions, which are the same as those under existing law for coal-tar colors, would defray only the cost of maintaining the listing and certification service; additional costs would be incurred for the enforcement and informational activities required by the establishment of a tolerance system. Enclosed herewith, as required by Public Law 801, 84th Congress, are statements of cost estimates and personnel requirements which would be entailed.

We should appreciate it if you would refer the enclosed draft bill, with the accompanying material, to the appropriate committee for consideration.

The Bureau of the Budget advises that there is no objection to the presentation of this proposed legislation to the Congress for its consideration.

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, August 7, 1959

Hon. LISTER HILL,
Chairman, Committee on Labor and Public Welfare,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: We understand that representatives of some of the industries that would be affected by S. 2197 (to be known as the Color Additive Amendments of 1959) have suggested to your committee an amendment to the bill relating to the requirements concerning analytical methods for color additives, and that an expression of our views on the amendment is desired.

Under the bill in its present form (p. 9, lines 3–16), the proposed section 706(b)(4) of the Federal Food, Drug, and Cosmetic Act would preclude the Secretary from listing a color additive for any use in or on food, drugs, or cosmetics unless the data before him establish—

"(A) that such use, under the conditions of use to be specified in the regulations, will be safe;

"(B) that practicable methods of analysis exist for determining the quantity of the pure dye and all intermediates and other impurities contained in such color additive; and

"(C) that practicable methods exist for determining the identity and quantity (i) of such additive in or on any article of food, drug, or cosmetic, and (ii) of any substance formed in or on such article because of the use of such additive."

The proposed amendment suggested by industry representatives would consolidate the matter contained in the above-quoted paragraphs *(b)* and *(c)* and, with appropriate editorial revision, transfer it to section 706 (b)(5), which begins on the same page and enumerates some of the most important factors which the Secretary must consider in passing on the safety of a proposed use of a color additive. As so amended, section 706(b) (4) and (5), beginning on page 9, line 3, and ending on page 10, line 9, of the bill, would read as follows:

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe.

[p. 5]

"(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

"(A) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

"(B) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

"(C) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

"(D) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive."

The net effect of the change would be to require the Secretary to determine whether, with respect to particular color additives and proposed listings, all of the analytical methods described both in the original bill and in the proposed amendment are needed and, to the extent that they are, to refuse a listing unless these methods exist and are made available to him, whereas, under the bill as originally introduced, the Secretary must refuse a listing unless all of the described methods of analyses are available to him, without regard to whether, with respect to a particular proposed listing of a color additive, such methods are in his judgment actually needed.

The proponents of the amendment believe that some of the requirements of the original bill, and in particular the requirement that there be practicable methods for determining the identity and quantity of any substance formed in or on food because of the use of a color additive, could not always be met in the present state of knowledge and that, in those cases in which there is no need for such a method of analysis for adequate public health protection, the requirement would unnecessarily bar the use of a color additive which would be perfectly safe.

The purpose of the requirement of the bill that there be practicable methods of analysis for determining the quantity of the pure dye and all intermediates and other impurities contained in a color additive is to enable the manufacturer of the color, and also this Department where we are asked to certify batches of color, to determine that the color in actual practice meets the requirements for purity and the definitional standards of our regulations and to facilitate enforcement. The purpose of the other requirements as to available practicable methods of analysis is to make possible effective enforcement of any conditions or limitations that may be put on the listing of a color for use in foods, drugs, or cosmetics. We, of course, regard practicability and facility of enforcement as essential elements of safety in determining whether a proposed use of a color additive is safe within the meaning of the bill.

[p. 6]

There are many circumstances where it would be necessary to have practicable analytical methods for all or most of the above-mentioned purposes. We can, however, visualize some situations in which these analytical methods, or some of them, would not be necessary for any of the purposes which we have mentioned and would thus not be essential in the interest of sound public health protection. We therefore recognize that in requiring such analytical methods to be available in all cases without regard to actual need the original bill goes further than absolutely necessary for public health protection.

Under the proposed change, we would consider ourselves bound to require those analytical methods specified in the bill for which, on the basis of our general knowledge or on the basis of the particular situation, we find that there is a need for the above-mentioned purposes, or otherwise in the interest of safeguarding the public health, and we would therefore feel bound to refuse to list a color where such needed methods are not available. At the same time, the proposed amendment would relieve us of the necessity of imposing these requirements where they are not needed.

We therefore would not object to the proposed change in the bill.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., August 12, 1959

Hon. LISTER HILL,
U.S. Senate, Washington, D.C.

DEAR SENATOR HILL: Reference is made to S. 2197. We have had an opportunity to consider the suggestions of members of your staff with regard to the status of coloring materials which are exempt from the provisions of the Food Additives Amendment, Public Law 85-929.

Materials which are generally recognized as safe for their intended use by experts qualified by training and experience to evaluate safety of foods are exempt from the provisions of the food additives amendment. We see no reason why such coloring materials as fall within this category and are found by the Secretary to be so classified should not be listed as suitable for use in food under the provisions of the color additive bill, S. 2197, and at the same time be exempt from the certification procedures provided for in that bill.

The language to reach this end is supplied herewith. We are satisfied that this same result would be obtained under the bill in any event.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary

EXPLANATION OF PRINCIPAL FEATURES AND PURPOSES OF THE COLOR ADDITIVE AMENDMENTS OF 1959

The letter of transmittal from the Secretary of Health, Education, and Welfare, briefly summarizes the general objectives of S. 2197, the principal reasons which gave rise to it, and previous [p. 7] amendments to the Federal Food, Drug, and Cosmetic Act which, in the case of food, show congressional endorsement of its key principle; i.e., recognition of the scientific soundness of considering the level and other conditions of use in determining the safety of a color additive. A fuller explanation is, however, necessary to an adequate understanding of the major provisions of the bill and their purposes against the background of existing law.

A. PRESENT LAW

Under present law, the treatment of color additives differs radically as between the so-called coal-tar colors and others. (For explanation of the technical difference between so-called coal-tar colors and others, see the discussion under "Major Changes Proposed.")

1. *Coal-tar colors.*—The act requires the Secretary to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, or cosmetics; and a food, drug, or cosmetic (other than a hair dye) is deemed adulterated if it bears or contains a coal-tar color other than from a certified batch (except that in the case of drugs this provision applies only where the coal-tar color is used for coloring purposes only). (See secs. 402(c), 406(b), 501(a)(4), 504, 601(e), 604, and 701(c) and (f) of the act.) Under these provisions, the Secretary is without power to admit a color to listing under tolerance limitations (*Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958)).

2. *Other colors.*—A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirement in the case of cosmetics or drugs (except as pretesting may be required for a coloring component as an incident to official clearance of a "new drug" under the "new drug" provisions of the act).

On the other hand, with respect to their use in food, non-coal-tar coloring materials which are classed as "food additives" under the recent Food Additives Amendment of 1958 (Public Law 85-929) are subject to a requirement of official safety clearance, and to the establishment of tolerance limitations and other conditions of safe use where necessary for public health protection, except that colors which were in commercial use before January 1, 1958, are allowed a grace period for compliance; this period will expire not later than March 6, 1961. Such "food additive" colors, however, are not subject to any requirement of "batch" certification even if, in view of the Administrator, this would be desirable for the protection of food processors and housewives using the color.

B. MAJOR CHANGES PROPOSED

The bill would change existing law in the following respects:

1. *Uniform criteria of admissibility.*—It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics (other than hair dyes). This would be accomplished by excepting color additives (as defined in the bill) from the term "food additive"; repealing the present provisions for listing and [p. 8] certification of coal-tar colors; enacting, as part of a single section (sec. 706), comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification (or exemption from certification); and making other amendments to the act to mesh with these provisions.

The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives, but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived. S. 2197 would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term "coal-tar color." The bill would therefore establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics.

2. *Safety-of-use principle.*—S. 2197 adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use (including maximum tolerance limitations) as are determined to be necessary to assure the safety of such use.

3. *Comprehensive lists.*—S 2197, however, retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors "generally recognized" by experts as safe for use. While there was justification in the case of the Food Additives Amendment of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—we do not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. To engraft such an exception on the bill would be retrogressive as compared with present law relating to coal-tar colors. If color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color.

4. *Certification and exemptions from certification.*—While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necesssary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations [p. 9] defining the color's identity. The committee believes, however, that power to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color. One of the amendments adopted by the committee provides that a color additive deemed safe under the provisions of the Food Additives

Amendment of 1956 shall be exempt from the requirement for certification.

5. *Effective date and transitional provisions.*—The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act, i.e., title I of the bill, would become effective as soon as the bill is enacted.

However, in order to allow on an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification (or exemption from certification in certain cases). The "commercially established" color additives falling under these transitional provisions are *(a)* those coal-tar colors of which a batch or batches were actually certified prior to the date of enactment of the bill, and *(b)* those non-coal-tar colors, and synthetic, beta-carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for protection of the public health during the period of provisional listing. The bill would permit establishment of a zero tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic, except that in the case of a coal-tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary.

In order to enable the Secretary to compile and promulgate a list of colors which are deemed provisionally listed without specific request to the Secretary, and in order to enable him to determine temporary tolerances for such colors, the Secretary would, after reasonable public notice for submission of data, be required, for the time being, to fix temporary tolerances at zero level with respect to those colors and uses thereof for which the data available to him do not establish a reliable basis for inclusion in a list of colors deemed provisionally listed and for determining the prevailing levels of use thereof prior to the enactment date.

In general, a provisional listing would terminate no later than the end of the 2½-year period beginning on that date of enactment. However, where necessary to complete the scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as practicable. Of course, a provisional listing of a color additive for any use, if not sooner terminated, would cease upon listing of the additive for such use under the permanent provisions of the bill.

[p. 10]

C. NEED FOR THE BILL

The interests of consumer protection and of the food, drug, cosmetic, and color industries combine to make urgent the need for enactment of this bill.

1. *Consumer protection.*—First. Under present law the Government has to perform extensive research to determine whether the colors now listed and being used are in fact harmless and suitable for use in food, drugs, and cosmetics. The bill would require industry to assume the burden of this testing, and would require the tests to be completed within 2½ years or, in individual cases, such additional testing period as is shown to be required and to be consistent with public-health protection. Further, it would allow the Secretary to place safe tolerance limitations on the amount of color that may be used and the products on which it may be used during this transition period; the Secretary has no such authority under present law.

Second. Other important aspects of consumer protection afforded by the bill are (*a*) that the pretesting requirement would be extended to those non-coal-tar colors, especially those used in cosmetics and drugs, to which it does not now apply, and (*b*) that the requirement of certification of batches of color, where necessary for the protection of the public health, would be extended to all colors.

Third. The use of color in foods, drugs, and cosmetics, though largely of value from the point of view of enhancing the marketability of the articles involved, is, in many cases, also in the consumer's interest and affirmatively desired by consumers. This is obviously so not only in the case of cosmetics, many of which are designed and purchased for the very purpose of imparting color, but also in the case of certain foods, e.g., margarine, where consumers demand artificial color. Housewives also frequently purchase certified color for use in home-prepared foods. In drugs, color additives are much used for ready identification, thus helping the pharmacist, the physician, the nurse, and the patient to avoid dangerous mistakes in choosing the wrong bottle or box. Thus, it is in the interest of the consumer that the law be changed so as to make available an adequate supply of colors of the safety of which, for particular uses, the consumer can be assured.

2. *Commercial interests.*—The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which, we believe, could be relieved for most established colors on a sound and permanent basis by enacting the provisions of S. 2197 without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by the Secretary.

[p. 11]

The technical provisions and approach of this bill are summarized in detail in the section-by-section analysis which follows.

SECTION-BY-SECTION ANALYSIS OF "COLOR ADDITIVE AMENDMENTS OF 1959"

I. INTRODUCTION

Under existing law, so-called coal-tar colors are regulated under the Federal Food, Drug, and Cosmetic Act through similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). Food containing a coal-tar color is deemed adulterated by section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406; section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food, and to provide for certifying batches of such colors. A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504; section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors. A cosmetic (other than a hair dye (defined to exclude eyelash and eyebrow dyes)) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604; section 604 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

Food colors which are not coal-tar colors are, when not generally recognized by experts as safe, regulated as "food additives" under the Food Additives Amendment of 1958 (Public Law 85–929). Under section 402 (a) (2) (C) of the act, a food which is, bears, or contains a "food additive" is deemed adulterated if the additive is unsafe within the meaning of section 409; and under section 409, the food additive is deemed unsafe unless it and its use (or intended use) conform to a regulation under section 409 announcing the conditions under which the additive may be safely used.

The present bill takes "color additives" out of the scope of the Food Additives Amendment of 1958; repeals the present provisions for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); enacts new, integrated provisions for the separate listing of suitable "color additives" safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary may find necessary to assure the safety of the uses permitted; provides for the certification (or exemption from certification) of listed color additives for such permitted uses; adapts the adulteration and other provisions of the act to the substantive and other changes involved in the abovementioned changes; and contains transitional provisions for commercially established colors.

[p. 12]

II. SECTIONAL ANALYSIS

Title I—Amendments to Federal Food, Drug, and Cosmetic Act

* * * * * * *

Section 102(a)

Paragraph (1) adds color additives to the exceptions from section 402(a)(2)(A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." This paragraph of the bill makes explicit, with regard to color additives, the interpretation of the Supreme Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958), that section 406(a) of existing law—which authorizes the establishment of tolerances for poisonous or deleterious substances added to food where the additive is required in the production of the food or cannot be avoided by good manufacturing practice—cannot serve as a basis for allowing the use of coal-tar colors where marketability of a food depends on such coloring. Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph (2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act [p. 13] as enacted by the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the provisos to section 402(c) with respect to the use of color on oranges. (See Public Law 86–2.) (Sec. 406(b) of the act would be repealed under another section of the bill.) The effect of these changes would be to (*a*) make the new provisions applicable to all color additives, whether or not they are coal-tar colors; (*b*) extend them to the color additive itself before being added to food; and (*c*) use the technique of the pesticide chemicals amendment and food additives amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended sec. 706) of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

Paragraph (3) adds to section 403 of the basic act a new subsection (l), whereby a food which is a color additive is deemed misbranded unless packaged and labeled in accordance with packaging and labeling requirements, if any, contained in regulations issued under section 706 (as amended by the bill). (Under the basic act's definition of "food," a color additive intended to be added to food is itself considered "food" before it is so added.) [p. 14]

Section 103

Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(e) of the act. The saving provisions of 1 U.S.C. 109, will, of course, apply to these repeals.

Subsection (b) amends section 706 of the act to make more flexible and, incidentally, bring together within a single section of the act, the Secretary's rulemaking authority with respect to the use of color additives in or on food, drugs, or cosmetics. (Under present law, sec. 706 contains only a provision which conditions the admitting to listing and certification of coal-tar colors upon the payment of fees. Cf. subsec. (e) of sec. 706 as amended by the bill.) The major provisions of the proposed section 706 are:

[p. 15]

* * * * * * *

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406 [(a)]

* * * * * * *

[(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.]

* * * * * * *

[p. 23]

LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

When Color Additives Deemed Unsafe

Sec. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be, unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii), has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption [p. 25] *pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).*

Listing of Colors

(b)(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2)(A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used, specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specfied in the regulations, will be safe: Provided, however, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this

subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term "food additive" because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201 (s).

(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(A) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

(B) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(C) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety [p. 26] *of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and*

(D) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive.

(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(8) If, having regard to the aggregate quantity of color additive

likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

Certification of Colors

(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: Provided, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of [p. 27] *the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.*

Procedure for Issuance, Amendment, or Repeal of Regulations

(d) The provisions of section 701(e), (f), and (g) of this Act shall apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsections (b), (c), or (e) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409 (f)(2); and

(2) the scope of judicial review of such order shall be in accordance with the third sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

Fees

(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

Exemptions

(f) The Secretary shall by regulation (issued without regard to subsection (d) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

[p. 28]

1.2f (2) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 1761, 86th Cong., 2d Sess. (1960)

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COLOR ADDITIVE AMENDMENTS OF 1960

JUNE 7, 1960—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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MR. HARRIS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 7624]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The admendments, as they appear in the reported bill, are as follows:

(1) On page 1, line 4, strike out "1959" and insert in lieu thereof "1960".

(2) On page 3, line 9, strike out the quotation mark, and immediately below line 9, insert the following:

> "(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

(3) On page 9, strike out lines 8 through 21 and insert in lieu thereof the following:

> "(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the pur-
>
> [p. 1]
>
> pose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food

additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

(4) On page 10, line 19, strike out "and".

(5) On page 10, line 25, strike out the period and insert in lieu thereof "; and".

(6) On page 11, immediately above line 8, insert the following:

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(7) On page 11, lines 10, 12, and 19, immediately after "found" insert "by the Secretary".

(8) On page 11, immediately below line 20, insert the following:

"(C) (i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701 (c)) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

"(ii) Within sixty days after the date of such referral or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary [p. 2] and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

(iii) Where—

"(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

"(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

"(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the

> Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(9) On page 17, line 5, immediately after "health" insert the following:

> *Provided*, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

[p. 3]

(10) On page 17, line 13, immediately after "shall" insert the following:

> , subject to the provisions of subparagraph (C) of subsection (b) (5) of this section,

(11) On page 17, lines 16 and 17, stike out "subsections (b), (c), or (e)" and insert in lieu thereof "subsection (b) or (c)".

(12) On page 17, immediately below line 20, insert the following:

> "(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;
>
> "(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b) (5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of

section 7(c) of the Administrative Procedure Act (5 U. S. C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

(13) On page 19, line 1, strike out "(1)" and insert in lieu thereof "(3)".

(14) On page 19, line 5, strike out "(2)" and insert in lieu thereof "(4)".

(15) On page 25, line 14, strike out "Regulations" and insert in lieu thereof:

Except as provided in subparagraph (C) of this paragraph, regulations

(16) On page 25, line 23, immediately after the period insert the following:

Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act, shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 [p. 4] as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended.

(B) If the Secretary, by regulation—

(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1)(E) of this subsection; or

(ii) has, pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a)(2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

(17) On page 28, line 6, strike out "(B)" and insert in lieu thereof "(D)".

[p. 5]

(18) On page 28, line 20, strike out "paragraph (1) (A) and (C)" and insert in lieu thereof "paragraphs (1) (A) and (C) of this subsection".

(19) On page 29, line 15, immediately after "product" insert the following: "poultry or poultry product,".

PURPOSE OF LEGISLATION

The purpose of this bill is to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerances, under which such additives may be safely used.

GENERAL SUMMARY

The committee bill—

(1) takes "color additives" out of the scope of the Food Additives Amendment of 1958;

(2) repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604);

(3) enacts new, integrated provisions for the separate listing of suitable "color additives," safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted;

(4) provides for the certification (or exemption from certification) of listed color additives for such permitted uses;

(5) adapts the adulteration and other provisions of the Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above-mentioned changes; and

(6) contains transitional provisions for commercially established colors.

HEARINGS

Extensive hearings were held by the committee on this legislation in January, February, March, and May 1960 and a large number of witnesses were heard. The committee also heard from a distinguished group of scientific experts, selected by the President of the National Academy of Sciences, which discussed the scientific problems involved in this legislation, with special emphasis on the Delaney anticancer clause.

BACKGROUND INFORMATION

Under the Federal Food, Drug, and Cosmetic Act the treatment of color additives differs radically as between so-called coal-tar colors and other colors.

1. *Coal-tar colors.*—The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived.

[p. 6]

So-called coal-tar colors are regulated under the act through similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). The act requires the Secretary of Health, Education, and Welfare to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, and cosmetics.

Food containing a coal-tar color is deemed adulterated under section 402(c) of the act unless the color is from a bath certified by the Secretary under section 406. Section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food and to provide for certifying batches of such colors.

A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504. Section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors.

A cosmetic (other than a hair dye, which is defined to exclude eyelash and eyebrow dyes) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604. Section 604 then directs the Secretary to provide for listing of coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

The Secretary of Health, Education, and Welfare is without authority to admit a coal-tar color to listing under tolerance limitations; it must be harmless per se in order for the Secretary to admit it to listing (*Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958)).

One exception to the prohibition against the listing of a coal-tar color under tolerance limitations was made by the Congress in Public Law 86–2 to permit the temporary listing and certification of the color Citrus Red No. 2 for the coloring of mature oranges under tolerances found to be safe by the Secretary of Health, Education, and Welfare.

2. *Other colors.*—A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirements in the case of cosmetics or drugs except as pretesting may be required for a coloring component as an incident to official clearance of a "new drug" under the "new drug" provisions of the act.

Non-coal-tar coloring materials used in food, when such materials are not generally recognized by experts as safe, are classified as "food additives" under the Food Additives Amendment of 1958 (Public Law 85–929). Under section 402(a) (2) (C) of the act, a food which is, bears, or contains a "food additive" is deemed to be adulterated if the additive is unsafe within the meaning of section 409. Under section 409 the food additive is deemed unsafe unless it and its use, or intended use, conform to a regulation issued by the Secretary announcing the conditions, including the establishment of tolerance limitations, under which the additive may be safely used. Food colors which were in commercial use before January 1, 1958, are allowed a grace period not later than March 6, 1961, for compliance with the provisions of the Food Additives Amendment of 1958. Such "food additive" colors, however, are not subject to any requirement of "batch" certification.

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NEED FOR LEGISLATION

The principal reasons which give rise to the need for this legislation may be summarized as follows:

1. The law with respect to coal-tar colors — and this comprises most synthetic colors — is not in consonance with modern concepts of consumer protection, in that it does not allow the Secretary of Health, Education, and Welfare to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, the Secretary must ban the use of such a color completely, as not being "harmless," if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe. For externally applied drugs and cosmetics, the same principle applies if toxicity appears in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use may be wholly safe.

Prior to delisting proceedings by the Department of Health, Education, and Welfare there were 19 colors listed for unrestricted use in food, drugs, and cosmetics, 69 colors listed for unrestricted use in drugs and cosmetics, and 30 colors listed for use only in externally applied drugs and cosmetics, a total of 118 straight colors listed for certification. Seven colors have been removed from the food, drug, and cosmetic list and have been relisted for external use in drugs and cosmetic colors, so that we now have 12 food, drug, and cosmetic colors, 69 unrestricted drug and cosmetic colors, and 37 drug and cosmetic colors for external use. The Department has proposed that other colors be removed from listing and certification.

The principle of allowing colors to be used under tolerance limitations was endorsed, in 1956, by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program of the Food and Drug Administration, as indicated by the following excerpt from the Committee's report:

> This Committee feels compelled to indicate that certification of a compound as "harmless and suitable for use" in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified (Report of the National Academy of Sciences-National Research Council Ad Hoc Advisory Committee to Review the Food and Drug Administration's Research Program on Coal-tar Dyes, June 1956).

2. The theoretically "perfect" public health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While, theoretically, only "harmless" colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many of the so-called colors on the list may in fact be toxic in some concentrations. Yet, the Secretary of Health, Education, and Welfare cannot take a particular color off the list until he establishes its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the [p. 8] established colors would have to be completed—primarily by industry—and during which the Secretary could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

3. There is a need for making applicable to all color uses and all types of color — whether they be coal-tar colors or others — the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present there are no provisions for the certification of non-coal-tar colors. There is, moreover, no pretesting

requirement for non-coal-tar color additives as such, other than food additives.

4. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by the Department of Health, Education, and Welfare.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress in temporary emergency legislation (Public Law 86–2) with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring mature oranges, after previous adoption of the "safe-for-use" principle in the Food Additives Amendment of 1958 (Public Law 85–929). In reporting upon the emergency legislation for citrus red No. 2, this committee said:

> It is specifically provided that the provisions of this bill will become inoperative on August 31, 1961, or before that time if general legislation affecting coloring materials for food is enacted by the Congress. The reason for the time limit is that this is emergency legislation, which will meet the immediate needs of the citrus industry without permanently engrafting on the basic Food, Drug, and Cosmetic Act a new

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> principle of tolerances for coal-tar colors which is not applicable to foods generally. The expiration date has been so fixed as to allow the Congress ample time to consider the application of this principle to all foods.
>
> It is the intention of the committee as soon as feasible to study amendments to the Federal Food, Drug, and Cosmetic Act dealing with color additives generally, since the need for such legislation has been amply demonstrated to this committee (86th Cong., 1st sess., H. Rept. 88).

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

EXPLANATION OF COMMITTEE BILL

The committee bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act, with a scientifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

Major changes proposed

The bill would change existing law in the following respects:

1. *Uniform criteria of admissibility.*—It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics (other than hair dyes). This would be accomplished by excepting color additives (as defined in the bill) from the term "food additive"; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section (sec. 706), comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification (or

exemption from certification); and making other amendments to the act to mesh with these provisions.

The bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it
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under the term "coal-tar color." The bill would therefore establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. The lack of consumer protection inherent in the absence of such a requirement was forcefully brought to the attention of Congress by the investigations and recommendations of the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, the Delaney committee in the 82d Congress, and by the hearings culminating in the enactment of the Food Additives Amendment of 1958.

2. *Safety-of-use principle.*—The bill adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use (including maximum tolerance limitations) as are determined to be necessary to assure the safety of such use.

3. *Delaney anticancer clause.*—One provision of the bill which aroused considerable controversy in the hearings on this legislation is proposed section 706(b) (5) (B) appearing on page 11, line 8, of the reported bill, and often referred to as the Delaney anticancer clause.

This clause provides that a color additive shall be deemed unsafe and shall not be listed for any use which will or may result in ingestion of all or any part of such additive if the additive is found to induce cancer when ingested by man or animal, or if it is found to induce cancer in man or animal by other tests, not involving ingestion, which are considered to be appropriate for the evaluation of the safety of additives for use in food.

This clause also provides that a color additive shall be deemed unsafe and shall not be listed for any use which will not result in ingestion of any part of such additive if, after tests which are appropriate for the evaluation of the safety of the additive for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

A similar anticancer clause is included in the Food Additives Amendment of 1958 to the Federal Food, Drug, and Cosmetic Act (Public Law 85–929).

There are many unknowns about cancer that are yet to be solved. We do know, however, that today cancer is second only to heart disease as a cause of death among the American people. Every year, approximately 250,000 people die of cancer in this country. Approximately 450,000 new cases of cancer are discovered each year. At any given time about 700,000 persons are under treatment for cancer.

Expert testimony before the committee showed that scientific inquiry into the incidence of cancer among certain occupational groups has been traced, in several instances, to specific substances involved in their environment. Laboratory experiments have shown that a number of substances when added to the diet of test animals have produced cancers of various kinds in the test animals. It is this fact—namely, that small quantities of certain materials over a period of time will cause abnormal cell growth in animals—that gave rise to the Delaney anticancer clause in the Food Additives Amendment.

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The Secretary of Health, Education, and Welfare very strongly urged the retention of the Delaney clause in the reported bill. The reason for his position may be summarized from his statement to the committee as follows:

> The preponderance of scientific evidence clearly dictates our position: Our advocacy of the anticancer proviso in the proposed color additives amendment is based on the simple fact that no one knows how to set a safe tolerance for substances in human foods when those substances are known to cause cancer when added to the diet of animals. I should like to underline again one statement in particular which I read earlier from the summary of Dr. [G. Burroughs] Mider's review of the role of certain chemical and physical agents in relation to cancer. It is this:
>
> *"No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop."*

This is why we have no hesitancy in advocating the inclusion of the anticancer clause.

Unless and until there is a sound scientific basis for the establishment of tolerances for carcinogens, I believe the Government has a duty to make clear—in law as well as in administrative policy—that it will do everything possible to put persons in a position where they will not unnecessarily be adding residues of carcinogens to their diet.

The population is inadvertently exposed to certain carcinogens. Ultraviolet light occurs in sunlight. The burning of most fuels produces some minute quantities of chemical compounds that elicit cancer in experimental animals, and some of the same agents can be identified in soot, tars, dusts, and similar residues—even from the atmosphere. In view of these facts, it becomes all the more imperative to protect the public from deliberate introduction of additional carcinogenic materials into the human environment.

Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority. We believe, however, that the issue is so important that the elected representatives of the people should have the opportunity of examining the evidence and determining whether or not the authority should be granted.

Many have oftentimes expressed the fond hope that the day is not far distant when we shall be able to control cancer. A dramatic breakthrough in this sense may never come. Rather, the progress—looked at from the standpoint of reducing the number of cases of cancer—may come only as we are willing to give heed to the kind of leads that are incorporated in the document prepared by Dr. Mider. It is clear that if we include in our diet substances that induce cancer when included in the diet of test animals, we are taking a risk. In the light of the rising number of cases of cancer, why should we take that risk? Why shouldn't the Government do every- [p. 12] thing possible to see to it that we do not involuntarily take that risk?

* * * * * * *

This, I believe, is as far as our discretion should go in the light of present scientific knowledge. We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to

> produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.
>
> Unless and until cancer research makes a breakthrough at this point, the principle in the anticancer clause is sound. (Statement by Hon. Arthur S. Flemming, Secretary of Health, Education, and Welfare, before the House Committee on Interstate and Foreign Commerce, January 26, 1960.)

The Secretary further stated that, even if the Delaney clause is deleted from the bill, he believes that he has the authority to apply the policy that is reflected in that clause but he urged the Congress to join with the executive branch in giving added assurance to the public by including the anticancer clause in the proposed color additives legislation.

The committee heard a large number of witnesses on the anticancer clause, including a distinguished panel of scientific experts on cancer selected by Dr. Detlev W. Bronk, President of the National Academy of Sciences.

One industry witness objected to any anticancer clause. Another witness argued that it is possible to establish safe tolerance levels for substances that produce cancer when fed to test animals. Some would have the ban on cancer producers apply only to colors that induce cancer when ingested in an amount and under conditions reasonably related to their intended use. And another witness proposed that the cancer clause be taken out of its present position in the bill and added with material language changes to section 705(b) (5) (A) so that it would become simply one of the factors for the Secretary to consider in evaluating the safety of a color additive.

It is evident that such proposed changes are intended to give the Secretary the right to establish tolerances for presumed safe levels of colors that produce cancer when tested under appropriate laboratory conditions. Thus, any of the proposals, if adopted, would weaken the present anticancer clause in the reported bill. For this reason all of the proposed changes were rejected by the committee.

The panel discussed in considerable detail the scientific problems that confront us in connection with determination of the cancer-producing potential of chemicals. They pointed out the difficulties of designing and conducting an experiment to determine whether a substance is a cancer producer for man and the difficulties in evaluating the test data after they are obtained.

Some of the panel members have suggested that despite these difficulties, in extraordinary cases, the Secretary of Health, Education, and Welfare should have the authority to decide that a minute amount of a cancer-producing chemical may be added to

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man's food after a group of scientists consider all the facts and conclude that the quantity to be tolerated is probably without hazard.

In commenting on this testimony, the Secretary of Health, Education, and Welfare said:

> The Department's position is that the proposed color additives legislation should include an anticancer clause that makes illegal the use of any color that will induce cancer when tested by appropriate methods. We believe this position to be the only sound public policy in view of the fact that our experts tell us present scientific techniques do not permit them to state unequivocally how much or how little of a substance that induces cancer when administered to animals will induce cancer when administered to man.
>
> * * * * * * *
>
> The rallying point against the anticancer provision is the catch phrase that it takes away the scientist's right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for a man a safe tolerance for a cancer-producing agent. Until cancer research makes a breakthrough at this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive. As I pointed out in my original testimony, the opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how this provision works. It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.
>
> So long as the outstanding experts in the National Cancer Institute and the Food and Drug Administration tell us that

they do not know how to establish with any assurance at all a safe dose in man's food for a cancer-producing substance, the principle in the anticancer clause is sound (statement by Hon. Arthur S. Flemming, Secretary of Health, Education, and Welfare before the House Committee on Interstate and Foreign Commerce, May 9, 1960).

In view of the uncertainty surrounding the determination of safe tolerances for carcinogens, the committee decided that the Delaney anticancer provision in the reported bill should be retained without change.

The committee adopted an amendment, discussed below, which provides for an ad hoc advisory committee to study and report on the question of whether a color additive is a carcinogen.

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4. *Comprehensive lists.*—The bill retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors "generally recognized" by experts as safe for use. While there may have been justification in the case of the Food Additives Amendment of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—the Secretary of Health, Education, and Welfare does not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color. It may be noted, however, that a committee amendment to the bill deems a color additive to be suitable and safe for the purpose of listing for use generally in food, where there is in effect a published finding of the Department that the substance is generally recognized as safe for its intended use within the meaning of the provisions exempting such substances from the Food Additives Amendments of 1958.

5. *Certification and exemptions from certification.*—While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic

impurities and otherwise complies with regulations defining the color's identity. The committee agrees with the Secretary of Health, Education, and Welfare, however, that authority to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color.

6. *Effective date and transitional provisions.*—The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act—i.e., title I of the bill—would become effective as soon as the bill is enacted.

However, in order to allow on an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification (or exemption from certification in certain cases). The "commercially established" color additives falling under these transitional provisions are *(a)* those coal-tar colors of which a batch or batches were actually certified prior to the date of enactment of the bill, and *(b)* those *non*-coal-tar colors, and synthetic beta-carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for the protection of the public health during the period of provisional listing. The bill would permit establishment of a zero

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tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic except that, in the case of a coal-tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary of Health, Education, and Welfare.

In order to enable the Secretary to compile and promulgate a list of colors which are deemed provisionally listed without specific request to the Secretary, and in order to enable him to determine temporary tolerances for such colors, the Secretary would, after reasonable public notice for submission of data, be required, for the time being, to fix temporary tolerances at zero level with respect to those colors and uses thereof for which the data available to him do not establish a reliable basis for inclusion in a list of colors deemed provisionally listed and for determining the prevailing levels of use thereof prior to the enactment date.

In general, a provisional listing would terminate no later than the end of the 2½-year period beginning on the date of enactment. However, where necessary to complete the scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as practicable. Of course, a provisional listing of a color additive for any use, if not sooner terminated, would cease upon listing of the additive for such use under the permanent provisions of the bill.

7. *Deception.*—A witness before the committee suggested amending proposed section 706(b) (6) to add the word "harmful" before the word "deception" so as to provide that the Secretary shall not list a color additive for a proposed use if the data before him show that such proposed use would "promote harmful deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act."

The Federal Food, Drug, and Cosmetic Act prohibits, among other things, the introduction of an adulterated or misbranded food, drug, or cosmetic into interstate commerce, or the adulteration of misbranding of any food, drug, device, or cosmetic in interstate commerce, or while held for sale after interstate shipment. Furthermore, the food additives amendment (sec. 409(c) (3) (B) of the act) specifically prohibits the Secretary from issuing a regulation prescribing the conditions under which a food additive may be safely used if a fair evaluation of the data before him shows that the proposed use of the additive would "promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act."

The committee is of the opinion that it would be unsound policy to legislate against *deception* of the consumer in the food additives law and against *harmful deception* of the consumer in the color additives law. Obviously, the provision against deception of the consumer should be identical under both sections of the law. It should be emphasized that we are dealing here solely with deception which would violate the law. Among the relevant provisions of the Food and Drug Act aimed at deception are those which deem

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a food to be adulterated—

> (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is (sec. 402(b)(3) and (4) of the Federal Food, Drug, and Cosmetic Act).

Examples of coloring practices that would promote deception of the consumer in violation of the basic act were cited by the Secretary of Health, Education, and Welfare as follows: (1) the use of artificial color in egg noodles to hide a deficiency in eggs, (2) the use of artificial color on immature apples or oranges to make the fruit appear mature, (3) the use of artificial color in tomato catsup or juice or canned tomatoes prepared from immature raw materials, and (4) the use of artificial color in stale red meat to make it appear fresh.

The Secretary of Health, Education, and Welfare, by letter dated April 21, 1960, has advised the committee that use of artificial coloring, under proper labeling declaration, on mature oranges would not promote deception in violation of the Federal Food, Drug, and Cosmetic Act. Likewise, the Food and Drug Administration, by letter dated June 2, 1960, has advised the committee that the use of safe coloring in oleomargarine or margarine, with appropriate label declaration, or in butter would not promote deception in violation of the act. These letters are included in the appendix to this report.

(8) Recommended amendments to Food Additives Amendment.—The Secretary of Health, Education, and Welfare recommended the adoption of two amendments to the Food Additives Amendment of 1958. These proposed amendments are:

> (1) A modification of the Delaney anticancer clause to provide that additives used in animal feed which do not adversely affect the animal and which leave no residue either in the animal after slaughter, or in any food product obtained from the living animal, be exempt from the provisions of the clause. The Secretary also suggested a corresponding change with respect to color additives.
>
> (2) A modification of the "prior sanction or approval" (grandfather) clause (sec. 201(s)(3) of the act).

The Secretary's letter of May 13, 1960, submitting these amendments is included in the appendix to this report.

The committee did not consider the above-mentioned amendments because they involved amendments to the food additive amendments which are not directly germane to this bill. They may be considered at a later date.

EXPLANATION OF PRINCIPAL COMMITTEE AMENDMENTS

(1) Agricultural chemicals affecting color (p. 3, beginning on line 10 of reported bill)

The committee was advised that certain pesticide chemicals used in fruit production have the effect not only of protecting the trees against plant diseases but also of supporting or otherwise affecting natural plant processes which thus result in the production of better color and finish in the fruit. Also, some plant growth regulators, [p. 17] when applied to plants, likewise enhance the development of normal color in the produce of such plants. Some fear has been expressed that such chemicals and plant regulators could be considered to fall within the scope of the definition of "color additive" in section 101(c) of the bill since they have the ability to promote the coloring of raw agricultural commodities.

The committee agrees with the Secretary of Health, Education, and Welfare that such chemicals and plant nutrients are not color additives within the meaning of the basic definition of color additive in this bill, since they merely promote the development of the natural color of produce as the result of the normal physiological processes of the plant or produce. To make this clear, however, the committee has inserted an amendment to the effect that the term "color additive" in section 101(c) of the bill shall not be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical which affects the color of fruit or other raw agricultural commodity which is the produce of the soil solely through its effect on plant metabolism or enzymatic processes either before or after harvest. Pesticide chemicals are regulated under section 408 of the Federal Food, Drug, and Cosmetic Act and under the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163; 7 U.S.C. 135—135k), and there is no necessity for subjecting them to additional regulation under the color additive amendments when their sole effect on color is through such metabolic or enzymatic processes.[1]

It is not the intention of the committee, however, to exempt from the provisions of this bill any chemical or nutrient if it also contains a dye, pigment, or other substance whose function is to impart color to the fruit or other raw agricultural commodity.

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[1] Under a recent amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (Public Law 86-139) nematocides, plant regulators, defoliants, and desiccants have been classified as pesticide chemicals.

The views of the Secretary of Health, Education, and Welfare in letters to the committee dated February 8, 1960, and April 21, 1960, and the letter of the Assistant Secretary of Agriculture dated April 14, 1960, expressing their views on this subject, in which the committee concurs, are shown in the appendix to this report.

(2) Color additives exempted under Food Additives Amendment (p. 9, beginning on line 8 of reported bill)

This committee amendment revises proposed section 706(b)(4) by transferring the provisions of subparagraphs (B) and (C) thereof, in consolidated and modified form, to proposed section 706(b)(5) (see discussion immediately below) and adding a proviso to the revised section 706(b)(4) providing that a color additive shall be deemed to be suitable and safe for listing for use generally in or on food while there is in effect a published finding by the Secretary declaring that such additive is exempt under the Food Additives Amendment of 1958 because of its being generally recognized by qualified experts as safe for its intended use as provided in section 201(s) of the act.

(3) Analytical methods for color additives (p. 11, beginning on line 1 of reported bill)

This committee amendment adds a new subparagraph (iv) to proposed section 706(b)(5)(A) in the bill, which consolidates and modifies the provisions of subparagraphs (B) and (C) of proposed section 706(b)(4) in the bill as introduced. These subsections deal

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with practicable methods of analysis for color additives and for determining the identity and quantity of such additives or their reaction products in foods, drugs, and cosmetics.

The net effect of the change would be to require the Secretary to determine whether, with respect to particular color additives and proposed listings, all of the analytical methods described both in the original bill and in the proposed amendment are needed and, to the extent that they are, to refuse a listing unless these methods exist and are made available to him, whereas, under the bill as originally introduced, the Secretary must refuse a listing unless all of the described methods of analysis are available to him, without regard to whether, with respect to a particular proposed listing of a color additive, such methods are in his judgment actually needed.

The proponents of the amendment believe that some of the requirements of the original bill, and in particular the requirement that there be practicable methods for determining the identity and quantity of any substance formed in or on food because of the use of a color additive, could not always be met in the present state of knowledge and that, in those cases in which there is no need for such a method of analysis for adequate public health protection, the requirement would unnecessarily bar the use of a color additive which would be perfectly safe. The committee amendment meets this objection without impairing consumer health protection.

(4) Ad Hoc Scientific Advisory Committee on Carcinogenicity of Additive (p. 11, beginning on line 21 of reported bill)

This committee amendment provides that in any proceeding for the issuance, amendment, or repeal of a regulation by the Secretary of Health, Education, and Welfare listing a color additive, any person who will be adversely affected may request that the petition or order thereon or the Secretary's proposal which is the subject of the proceeding be referred to an advisory committee for a report and recommendations with respect to any matter arising under proposed section 706(b)(5)(B) of the bill, commonly referred to as the Delaney anticancer clause, if such matter is involved in such proposal or order and requires the exercise of scientific judgment.

Upon such request, the Secretary shall forthwith appoint an advisory committee and shall refer to it for study and for a report and recommendations the question arising under section 706(b)(5)(B). The Secretary may also refer such a matter to such an advisory committee on his own initiative. The petitioner as well as representatives of the Department of Health, Education and Welfare shall have the right to consult with the advisory committee.

The request for referral, or the Secretary's referral on his own initiative, may be made at any time before, or within 30 days after, publication of the Secretary's order acting upon the petition or proposal.

Within 60 days after the referral date or within an additional 30 days if necessary, the advisory committee shall certify to the Secretary a report and recommendations. Within 30 days after such certification, and after giving due consideration to all the information before him, including the report, the Secretary shall by order confirm or modify any order theretofore issued, or if no such prior order has been issued, he shall by order act upon the petition or other proposal.

[p. 19]

Where by reason of section 706(b)(5)(B) the Secretary has initiated a proposal to remove from listing a color additive previously listed and a request has been made for referral of such a proposal to an advisory committee, the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations and he has considered such recommendations unless the Secretary finds that emergency conditions exist necessitating the issuance of an order.

The committee intends by the term "emergency conditions" to mean, in general, a condition which requires immediate action in order to avoid imminent hazard to public health.

The advisory committee shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background. In the unlikely event that the National Academy of Sciences is unable or refuses to act, the Secretary shall select the members of the advisory committee. The size of the committee shall be determined by the Secretary.

Any report, recommendations, underlying data, and reasons certified to the Secretary by such advisory committee shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedures Act (5 U.S.C. 1006(c)) (p. 18, beginning on line 11 of reported bill).

The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing (p. 18, beginning on line 17 of reported bill).

(5) Color additive deemed to be safe under the proviso in section 706(b)(4) need not be certified (p. 17, beginning on line 5 of reported bill)

This committee amendment provides that any color additive which has been listed as suitable and safe for use generally in or on food by reason of the proviso in proposed section 706(b)(4), discussed above, need not be certified by the Secretary under proposed section 706(c) in this bill.

(6) Time schedule governing action on a petition (p. 17, beginning on line 21 of reported bill)

This committee amendment sets up a time schedule governing the action on a petition to the Secretary for the issuance, amendment, or repeal of a regulation, except where matters are referred to an advisory committee. As stated above, a separate time schedule is prescribed for cases involving advisory committees.

Notice of the proposal made by a petition must be published in general terms by the Secretary within 30 days after filing, and the Secretary's order acting upon such proposal shall be issued within

90 days after the date of the filing of the petition. The Secretary may extend the 90-day period up to but not exceeding 180 days as he deems necessary to enable him to study and investigate this petition. This is the same time schedule as is provided in the Food Additives Amendment of 1958.

[p. 20]

(7) *Review of regulation by Secretary terminating or placing a tolerance limitation on a provisional listing* (p. 26, beginning on line 7 of reported bill)

This committee amendment provides that if the Secretary of Health, Education, and Welfare has, by regulation issued pursuant to the transitional provisions of this legislation, terminated a provisional listing (or deemed provisional listing) of a color additive or a particular use thereof, or if he has established, or made more restrictive, a tolerance limitation or other restriction or requirement with respect to an already effective provisional listing, any person who may be adversely affected by such action may petition the Secretary for an amendment to revoke or modify such action, but such petition will not operate to stay or suspend the effectiveness of such action. The Secretary must afford all interested persons an opportunity to present their views on the proposal of the petition after which the Secretary shall act on the petition by published order.

Any person adversely affected by this order may, within 30 days, file objections thereto, state reasonable grounds therefor, and request a public hearing upon such objections which shall be granted. Based on the evidence adduced at such hearing, the Secretary shall issue an order which may reinstate a terminated provisional listing or alter a previously established temporary tolerance limitation, or alter any other limitation established by him, only if in his judgment the evidence shows that such action will be consistent with the protection of the public health. Such order shall be subject to judicial review in accordance with section 701 (f) of the Federal Food, Drug, and Cosmetic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. The court may not stay or suspend the Secretary's order pending conclusion of judicial review.

REPORTS FROM EXECUTIVE DEPARTMENTS AND AGENCIES

The reports from the various executive departments and agencies on H. R. 7624 (S. 2197) are found in the appendix to this report.

The Secretary of Health, Education, and Welfare estimated the cost of enforcing this legislation to be approximately $1 million during the first year of operation and close to $900,000 a year thereafter. The details on this estimate are contained in the Secretary's letter of May 29, 1959, reproduced in the appendix to this report.

SECTION-BY-SECTION ANALYSIS OF "COLOR ADDITIVE AMENDMENTS OF 1960"

I. INTRODUCTION

Under existing law, so-called coal-tar colors are regulated under the Federal Food, Drug, and Cosmetic Act through similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). Food containing a coal-tar color is deemed adulterated by section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406; section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food, and to provide for certifying batches of such colors. A drug containing a coal-tar color solely for coloring [p. 21] purposes is deemed adulterated by section 501(a) (4) unless the color is from a batch certified by the Secretary under section 504; section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors. A cosmetic (other than a hair dye (defined to exclude eyelash and eyebrow dyes) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604; section 604 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

Food colors which are not coal-tar colors are under existing law when not generally recognized by experts as safe, regulated as "food additives" under the Food Additives Amendment of 1958 (Public Law 85–929). Under section 402(a) (2) (C) of the act, a food which is, bears, or contains a "food additive" is deemed adulterated if the additive is unsafe within the meaning of section 409; and under section 409, the food additive is deemed unsafe unless it and its use (or intended use) conform to a regulation under section 409 announcing the conditions under which the additive may be safely used.

The present bill takes "color additives" out of the scope of the Food Additives Amendment of 1958; repeals the present provisions for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); enacts new, integrated provisions for the separate listing of suitable "color additives" safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary may find necessary to assure the safety of the uses permitted; provides for the certification (or exemption from certification) of listed color additives for such permitted uses; adapts the adulteration and other provisions of the act to the substantive and other changes involved in the above-mentioned changes; and contains transitional provisions for commercially established colors.

[p. 22]

II. SECTIONAL ANALYSIS

Title I—Amendments to Federal Food, Drug, and Cosmetic Act

* * * * * * *

Section 102(a)

Paragraph (1) adds color additives to the exceptions from section 402(a)(2)(A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph (2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act as enacted by the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the provisos to section 402(c) with respect to the use of color on oranges. (See Public Law 86–2.) (Sec. 406(b) of the act would be repealed under another section of the bill.) The effect of these changes would be to *(a)* make the new provisions applicable to all color additives, whether or not they are coal-tar colors; *(b)* extend them to the color additive itself before being added to food; and *(c)* use the technique of the pesticide chemicals amendment and food additives amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended sec. 706) of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

Paragraph (3) adds to section 403 of the basic act a new subsection (l), whereby a food which is a color additive is deemed misbranded unless packaged and labeled in accordance with packaging and labeling requirements, if any, contained in regulations issued under section 706 (as amended by the bill). (Under the basic act's definition of "food," a color additive intended to be added to food is itself considered "food" before it is so added.)

[p. 23]

Section 103

Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(c) of the act. The saving provisions of 1 U.S.C. 109, will, of course, apply to these repeals.

Subsection (b) amends section 706 of the act to make more flexible and, incidentally, bring together within a single section of the act, the Secretary's rulemaking authority with respect to the use of color additives in or on food, drugs, or cosmetics. (Under present law, sec. 706 contains only a provision which conditions the admitting to listing and certification of coal-tar colors upon the payment of fees. Cf. subsec. (e) of sec. 706 as amended by the bill.) The major provisions of the proposed section 706 are:

[p. 24]

* * * * * * *

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,

August 7, 1959.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: We understand that representatives of some of the industries that would be affected by H.R. 7624 (to be known as the Color Additive Amendments of 1959) have suggested an amendment to the bill relating to the requirements concerning analytical methods for color additives.

Under the bill in its present form (p. 9, lines 3–16), proposed section 706(b)(4) of the Federal Food, Drug, and Cosmetic Act would preclude the Secretary from listing a color additive for any use in or on food, drugs, or cosmetics unless the data before him establish—

"(A) that such use, under the conditions of use to be specified in the regulations, will be safe;

"(B) that practicable methods of analysis exist for determining the quantity of the pure dye and all intermediates and other impurities contained in such color additive; and

"(C) that practicable methods exist for determining the identity and quantity (i) of such additive in or on any article of food, drug, or cosmetic, and (ii) of any substance formed in or on such article because of the use of such additive."

The proposed amendment suggested by industry representatives could consolidate the matter contained in the above-quoted paragraphs (B) and (C) and, with appropriate editorial revision, transfer it to section 706(b)(5), which begins on the same page and enumerates some of the most important factors which the Secretary must consider in passing on the safety of a proposed use of a color additive. As so amended, section 706(b) (4) and(5), beginning on page 9, line 3, and ending on page 10, line 10, of the bill, would read as follows:

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe.

"(5)(A) in determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

"(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

"(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

"(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive."

[p. 77]

The net effect of the change would be to require the Secretary to determine whether, with respect to particular color additives and proposed listings, all of the analytical methods described both in the original bill and in the proposed amendment are needed and, to the extent that they are, to refuse a listing unless these methods exist and are made available to him, whereas, under the bill as originally introduced, the Secretary must refuse a listing unless all of the described methods of analyses are available to him, without regard to whether, with respect to a particular proposed listing of a color additive, such methods are in his judgment actually needed.

The proponents of the amendment believe that some of the requirements of the original bill, and in particular the requirement that there be practicable methods for determining the identity and quantity of any substance formed in or on food because of the use of a color additive, could not always be met in the present state of knowledge and that, in those cases in which there is no need for such a method of analysis for adequate public health protection, the requirement would unnecessarily bar the use of a color additive which would be perfectly safe.

The purpose of the requirement of the bill that there be practicable methods of analysis for determining the quantity of the pure dye and all intermediates and other impurities contained in a color additive is to enable the manufacturer of the color, and also this Department where we are asked to certify batches of color, to determine that the color in actual practice meets the requirements for purity and the definitional standards of our regulations, and to facilitate enforcement. The purpose of the other requirements as to available practicable methods of analysis is to make possible effective enforcement of any conditions or limitations that may be put on the listing of a color for use in foods, drugs, or cosmetics. We, of course, regard practicability and facility of enforcement as essential elements of safety in determining whether a proposed use of a color additive is safe within the meaning of the bill.

There are many circumstances where it would be necessary to have practicable analytical methods for all or most of the above-mentioned purposes. We can, however, visualize some situations in which these analytical methods, or some of them, would not be necessary for any of the purposes which we have mentioned and would thus not be essential in the interest of sound public health protection. We therefore recognize that in requiring such analytical methods to be available in all cases without regard to actual need the original bill goes further than absolutely necessary for public health protection.

Under the proposed change, we would consider ourselves bound to require those analytical methods specified in the bill for which, on the basis of our general knowledge or on the basis of the particular situation, we find that there is a need for the above-mentioned purposes, or otherwise in the interest of safeguarding the public health, and we would therefore feel bound to refuse to list a color where such needed methods are not available. At the same time, the proposed amendment would relieve us of the necessity of imposing these requirements where they are not needed.

We therefore would not object to the proposed change in the bill.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary

[p. 78]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

February 8, 1960

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: It has come to my attention that two questions have been raised concerning the scope of the proposed color additives legislation now being considered by your committee (S.2197 and H.R. 7624). Since these questions were not covered by my testimony on January 26, I am taking this opportunity of letting you have the views of our Department on them.

A representative of the packaging industry has expressed to us an apprehension that the Department's proposed legislation might be construed as applying to coloring materials used in food wraps and other food packaging materials even where the color does not migrate from the wrap to the food or, if there is migration, where it is so slight that it would cause no color in food discernible by the unaided eye.

It is our view that the color additives amendment would not apply to color materials in food wraps that do not migrate from the wrap to the food.

Additionally, it is our view that the bill is intended to regulate substances

that color or are capable of coloring food to a degree apparent to the naked eye. Thus, a component of food packaging that migrated into food but did not change its color in the ordinary sense of the term would continue to be regulated, if necessary, under the food additives amendment and would not become subject to the proposed color additives bill.

The second question relates to pesticide chemicals as defined in section 201(q) of the Federal Food, Drug, and Cosmetic Act. We are advised that certain fungicides used in fruit production have the effect not only of protecting the tree against plant diseases but also of effecting or supporting natural plant processes so the plant produces better color and finish in the fruit; and some plant growth regulators, when applied to plants, likewise enhance the development of normal color in produce derived from them.

It is our view that pesticide chemicals used in this way are not color additives within the meaning of the proposed legislation and do not impart an artificial color to the raw agricultural commodities. Rather, they promote the development of the natural color of produce as a result of the normal physiological processes of the plant. The legislation which we drafted was not intended to apply to pesticide chemicals which enhance color by affecting or supporting natural plant processes and we would expect to continue to regulate pesticide chemicals, if the bill is enacted in its present form, under the pesticide chemicals amendment and not the color additives amendment.

Sincerely yours,

ARTHUR S. FLEMMING, ***Secretary***

[p. 79]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
April 11, 1960

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The purpose of this letter is to recommend a correction in the hearing provision in title I of the proposed "Color Additive Amendments of 1959" (H.R. 7624 and S. 2197) now pending before your committee.

As drafted by this Department and submitted to Congress, and as contained in these bills, the hearing provision would, through an inadvertent cross-reference to the subsection on fees, provide for hearing and judicial review not only with respect to the issuance, amendment, or repeal of regulations relating to the listing and certification of color additives, but also with respect to regulations establishing fees for such listing and certification.

Under present law as consistently interpreted by us since its enactment, the issuance or amendment of regulations establishing schedules of fees for the listing and certification of coal-tar colors is not subject to hearing or judicial review (section 706 of Federal Food, Drug, and Cosmetic Act). This likewise holds true in the case of fees for certification services for insulin or antibiotics, fees for the pesticide regulation service, and fees for seafood inspection (sections 408(o), 506, 507, 702A). The establishment of such fees is purely a matter of cost accounting and, since the services must be self-sustaining, the fees are automatically kept at the appropriate level through auditing of expenditures by the General Accounting Office. To provide for

hearing and judicial review with respect to the establishment of fees would thus serve no useful purpose and, on the other hand, might cause delay which could seriously impede or make impossible the performance of the services in question.

We therefore recommend that the provisions of these bills be corrected by changing the phrase "subsections (b), (c), or (e) of this section" (H.R. 7624, p. 13, line 6; S. 2197, p. 13, line 9) to read "subsection (b) or(c) of this section."

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., April 21, 1960

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: On January 29, you indicated during the hearings on pending color additive legislation (H.R. 7624 and S. 2197) that you would like to have our views on the various amendments proposed by witnesses other than those representing this Department. Accordingly, we have reviewed the record of the hearings and are glad to offer the following comments.

The amendments proposed by the witnesses fall into four principal categories:

1. There are a number of suggestions for change in the scope of the bills. [p. 80]

2. There are several recommendations with respect to the substantive criteria for listing colors, including a number of adverse comments on the anticancer clause in the Department's proposal as contained in H.R. 7624. The criticisms of the bill's anticancer clause also extend to the clause from which it is derived, i.e., the so-called Delaney proviso in the Food Additives Amendment of 1958.

3. A number of suggestions are made on procedural points, both with respect to the permanent part (title I) and the transitional part (title II) of the bill.

Additionally, one individual, Mr. Frank Schell, of Florida, has written to the committee proposing an entirely new bill to be substituted for the Department's bill.

Our comments on these various items, except the anticancer clause are enclosed herewith (enclosure I). I expect to testify further on the anticancer clause. There is enclosed herewith (enclosure II) a draft of a provision which would accord an opportunity for hearing with respect to certain regulatory actions under the transitional part of the bill, under the conditions stated in my testimony. There is enclosed (enclosure III) a draft amendment to the proposed section 706(d) of the bills, to incorporate time limits in the rulemaking procedure of the legislation if the committee should wish to do so. Also there is enclosed (enclosure IV) a draft amendment to section 203(d)(2)(A) of the bill to make it clear that funds and regulations dealing with the cost of certifying coal-tar colors under section 706 of the basic act, shall continue to be available and in effect, respectively, for the purposes specified in section 706 as amended by the proposed bill.

In summary, we are opposed to all the amendments proposed by the witnesses, except (1) a clarifying amendment on agricultural chemicals, in the form contained in enclosure I agreed upon by us with the Department of Agriculture, and (2) the amendments set forth in enclosures II and III. As between the repective versions of S. 2197 and H.R. 7624, we have already advised that the changes contained in S. 2197 as passed by the Senate are acceptable to us, except that we recommend inclusion of the anticancer clause of H.R. 7624 with a modification relating to animal feed similar to the one we are developing for the Delaney proviso to the Food Additives Amendment of 1958. We have also recommended, by letter dated April 11, 1960, a technical correction in section 706(d).

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary*

[Enclosure 1]

COMMENTS ON AMENDMENTS TO S. 2197 OR H.R. 7624, PROPOSED BY NONGOVERNMENTAL WITNESSES

I. SCOPE OF BILL

1. Nature, source, or type of action of the coloring material

(a) * * *

(b) *Agricultural chemicals.*—Several witnesses suggested that pesticide chemicals be exempted from the coverage of the color additives legislation. A representative of the National Agricultural Chemicals Association, on the other hand, indicated that the [p. 81] Department's position as to the interpretation of the bill—i.e., that chemicals affecting color of fruit or other produce merely through their effect on plant metabolism do not "impart color" within the meaning of the bills—as submitted in our letter of February 8, 1960, to you, would meet the needs of the association. However, by letter, the association has, we understand, requested that this position be incorporated in the language of the bill rather than left to legislative history. The Department of Agriculture also favors this. We have no objection to incorporating the position in the bill itself and suggest that the following language—jointly developed by this Department and the Department of Agriculture, and submitted to the committee by that Department by letter dated April 14, 1960—be added as subparagraph (3) to the definition of the term "color additive:"

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

More sweeping language suggested by the association and some other witnesses, which would mandatorily exempt a pesticide chemical even though that chemical also acts as a dye would be seriously objectionable since it would result in our list of food colors being incomplete and would admit of circumventing the certification provisions of the bill through the development of combined pesticide-dye chemicals. We invite attention to the fact that the bill already excepts from the term "color additive" any material "which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring."

* * * * * * *

To avoid any misunderstanding, we emphasize that the Department has no objection to the artificial coloring, under proper labeling declaration, of mature oranges. We have given this assurance to the citrus industry, we have stated it for the record at the hearings on the present bills, and we repeat it here.

* * * * * * *

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
May 13, 1960.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: On May 9, 1960, when I appeared before your committee with regard to proposed color additives legislation, you requested that we comment on a proposal that has been made for amending the anticancer clause of H.R. 7624. As we understand the proposal, it would change section 706(b) (5) (B) (i) so that it reads:

"(B) A color additive (i) shall be deemed unsafe and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if it is found, after tests which are appropriate for the evaluation of the safetly of additives for use in food, to induce cancer in man or animal, * * *." (Interlined material present in original bill, but to be deleted.)

[p. 82]

The deletion of the interlined language from the proposed color additives bill, and deletion of comparable language from the anticancer clause of the Food Additives Amendment of 1958, in view of the past history of the anticancer clauses, is obviously designed to weaken the anticancer clause and to allow room for the contention that our Department should establish tolerances to permit chemicals in food even though they had been found to induce cancer when fed. This would serve no purpose except to lead to extended litigation on this issue in the courts.

As you know from my testimony on January 26 and again on May 9, 1960, we believe there is no sound scientific basis at this time for establishing tolerances to allow carcinogens to be added to food.

We recommend that the proposed change not be adopted.

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, May 13, 1960.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: As you know, in my testimony before your committee on the color additive bills (H.R. 7624, S. 2197), I explained the need for modification of the Delaney (anticancer) proviso in the Food Additives Amendment of 1958 insofar as animal feed is concerned, and the need for modification of the so-called grandfather clause (sec. 201(s)(3)) of the food additives amendment, and stated that we were developing language to carry out these recommendations. I also suggested that adoption of a parallel modification of the anticancer clause of H.R. 7624 would be appropriate concomitantly with modification of the Delaney proviso.

At the close of my last appearance before the committee, you requested that we submit the technical language which we had in mind to carry out our recommendations, and you indicated that the record would be held open to the end of this week.

We are therefore enclosing, for the consideration of the committee, proposed amendments to the pending color bills which would carry out these recommendations. The two amendments on food additives are in a measure complementary to each other and, we believe, should be enacted at the same time. In view of their urgency, and the close relation of one of these amendments to the proposed modification of the anticancer clause of H.R. 7624, we hope that they will be included in the pending legislation.

There is also enclosed herewith a further explanation of the need for, and purposes of, the proposed changes in the Food Additives Amendment of 1958.

We should appreciate the inclusion of this letter and of the enclosures in the record of the hearings on H.R. 7624 and S. 2197.

[p. 83]

We are advised by the Bureau of the Budget that it perceives no objection to the submission of these proposals.

Sincerely yours,

ARTHUR S. FLEMMING,
Secretary.

[p. 84]

EXPLANATION OF NEED FOR, AND PURPOSES OF, ENCLOSED DRAFT AMENDMENTS TO GRANDFATHER CLAUSE AND ANTICANCER (DELANEY) PROVISO OF FOOD ADDITIVES AMENDMENT OF 1958 (FOR INCLUSION IN COLOR ADDITIVE BILL WITH PARALLEL MODIFICATION (ALSO ENCLOSED) OF ANTICANCER CLAUSE OF H.R. 7624)

The enclosed draft amendments to the color additive legislation would make two changes in those provisions of the Federal Food, Drug, and Cosmetic Act which were added to that act by the Food Additives Amendment of 1958 (Public Law 85–929), approved September 6, 1958.

Prior to the enactment of that amendment, pretesting and safety-clearance requirements applied, in general, under the act only to so-called pesticide chemicals used in or on raw agricultural commod- [p. 85] ities (as provided by Public Law 518, 83d Cong.), except that drugs used in animal feed or in other food, or administered directly to animals raised for food production, were subject to safety clearance under the new-drug provisions of the act (sec. 505). The Food Additives Amendment of 1958 (Public Law 85–929) further strengthened the public-health protection afforded by the act, by prohibiting any food additive which has not been adequately tested to establish affirmatively its safety for food use as determined through a safety-clearance procedure established by that amendment.

The underlying philosophy of the Food Additives Amendment of 1958 is that any reasonable doubt as to the safety of an additive should be resolved against permitting its use. Moreover, in line with this basic philosophy—and in the light of scientific evidence before the House committee that present scientific knowledge is not sufficient for determining a safe tolerance for the human diet in the case of a substance which, when included in the diet of test animals or otherwise administered to such animals through relevant tests, induces cancer in such animals—the Congress inserted in the law a proviso (known as the Delaney proviso) which bars a substance completely for food use if it is "found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

The experience so far had under Public Law 85–929, however, has disclosed a need for two modifications of the food additives amendment which would better carry out its public-health objective and remove certain inequities.

1. Grandfather clause

In enacting the Food Additives Amendment of 1958, Congress decided, in accordance with our recommendations, that in view of its public-health objective it should in general apply not only to new additives and new uses of existing additives, but also to uses of additives already commercially established, subject to transitional provisions intended to allow a reasonable time for compliance with the new pretesting requirements and safety-clearance procedure. However, in order to avoid useless paperwork, the amendment excluded from its scope two categories of additives (in addition to pesticide chemicals for raw agricultural commodities), i.e., any additive which is generally recognized by experts as safe (such as salt, pepper, sugar, etc.) and also "any substance used in accordance with a sanction or approval granted prior to the enactment of [the Food Additives Amendment] pursuant to [the Federal Food, Drug, and Cosmetic] Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following)."

Thus, while the last-quoted clause (which is now sec. 201(s) (3), but will be redesignated by the color additive bills as sec. 201(s) (4), of the Federal Food, Drug, and Cosmetic Act) is often for convenience referred to as the "grandfather" clause of the Food Additives Amendment, its purpose was not to confer any vested right in a prior sanction or approval of an additive, but merely to avoid the need for pro forma resort to the safety-clearance procedure of the amendment when the safety of the additive and of its particular use has been satisfactorily established through a prior sanction or approval. It was clearly understood that the so-called [p. 86] "grandfather" clause would be applicable only so long as the prior sanction or approval remained in effect and that, as stated in the explanation of this Department's draft bill from which the Food Additives Amendment was derived, the clause "would not prevent rescission of such a sanction or approval, and subsequent inclusion of the additive under the bill, if the particular use of the additive is subsequently found to be toxic or of doubtful safety." (Hearings on food additives before a subcommittee of the House Committee on Interstate and Foreign Commerce, 85th Cong. (1957 and 1958), p. 28, at p. 35.) See also 21 C.F.R., sec. 121.3; 24 F.R. 2434, Mar. 28, 1959, which established certain notice requirements for withdrawal or modification of such a prior sanction or approval.)

In submitting the grandfather clause to Congress, we had primarily in mind official advice contained in letters of the Food and Drug Administration (so-called trade correspondence) to members of the food and chemical industries in response to inquiries from them with respect to the interpretation or application of the Federal Food, Drug, and Cosmetic Act. Such advice, not being legally binding, could, of course, be withdrawn at any time without formal proceedings. However, there are also in effect certain prior "sanctions" or "approvals" under the act—particularly those granted for new drugs under section 505 of the act—which, though granted in the first instance only on the basis of what was considered an affirmative showing of safety, cannot thereafter be withdrawn unless the original application contained an untrue statement of a material fact or unless the Government can establish—on the basis of clinical experience, new test methods, or methods not previously deemed reasonably applicable—that the article is unsafe. This situation, of course, is contrary to the underlying premise of the grandfather clause that the grandfather clause would always become inapplicable when a previously sanctioned use of a chemical additive to food was found to be of doubtful safety. The law should make it very clear that establishing merely a reasonable doubt as to the safety of any additive, in the light of all available data, would be an adequate basis for withdrawal of any sanction or approval with respect to it.

This creates a situation which is inconsistent with the abovementioned basic philosophy and public-health objective of the Food Additives Amendment, and, in the case of a cancer-inducing chemical, with the anticancer proviso of that amendment. In the second place, it operates inequitably as between a person who holds an effective new-drug application, antedating Public Law 85–929, with respect to a drug manufactured by him for food use and who is thus protected by the grandfather clause because it is not shown to be unsafe but on which there may be doubt as to its safety, and another person who desires to make and market the same drug for the same purpose but who does not come within the grandfather clause and cannot obtain clearance under the Food Additives Amendment because the drug is banned by the anticancer proviso or because for other reasons its safety cannot be affirmatively demonstrated.

We therefore recommend amendment of the grandfather clause so that, whenever on the basis of the information available to the Secretary, he finds (after appropriate notice) that there is reasonable doubt as to the safety of the use of an additive sanctioned or approved pursuant to the Federal Food, Drug, and Cosmetic Act [p. 87] before enactment of Public Law 85–929, the grandfather clause will, with respect to that sanction or approval, no longer apply, and the safety-clearance requirements of the Food Additives Amendment will apply, without regard to any other requirements of the Food Additives Amendment will apply, without regard to any other requirements of the act relating to suspension or revocation of such previous sanction or approval. If, in such a case, the additive is a carcinogen, this, of course, will mean that it is thereafter subject to the above-quoted anticancer (Delaney) proviso, except as proposed below with respect to animal feed.

2. Modification of Delaney proviso

[p. 88]

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DEPARTMENT OF AGRICULTURE,
Washington, D.C., August 11, 1959.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR CONGRESSMAN HARRIS: This is in reply to your request of June 11, for a report on H.R. 7624, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

This Department would have no objection to enactment of the proposed legislation. The proposed legislation would enable the Secretary of Health, Education, and Welfare to take a realistic position with respect to the use of colors in food products, many of which are agricultural products.

The bill would enable the Secretary of Health, Education, and Welfare to establish tolerance limitations and other conditions of safe use for all color additives in or on foods, drugs, and cosmetics, in a manner similar to that set forth in the Food Additives Amendment of 1958. Under existing law the said Secretary may not establish tolerance limitations for coal-tar colors. A color additive would be deemed unsafe under the proposed bill if, among other things, it is found after tests which are appropriate for the evaluation of such additives to induce cancer in man or animals. The proposed legislation also contains a provision that its terms should not be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of the Poultry Products Inspection Act. This provision is also considered to be consistent with and in no way modifying the provisions of section 902(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392) which exempts meat and meat food products from the terms of that act to the extent of the application thereto of the Meat Inspection Act. Section 18 of the Poultry Products Inspection Act contains an exemption with respect to poultry and poultry products similar to that contained in section 902(b) of the Federal Food, Drug, and Cosmetic Act for meat and meat food products.

We believe that all dyes and colorings for use in or on foods, drugs, and cosmetics should be subject to the same principles presently applicable to food additives. The Secretary of Health, Education, and Welfare should be permitted to establish tolerances for these materials. Enactment of the proposed legislation will avoid such special legislation as that enacted recently permitting the addition of coloring to oranges (Public Law 86-2, approved March 17, 1959).

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

E. L. PETERSON, *Acting Secretary*.

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DEPARTMENT OF AGRICULTURE,
Washington, D.C., May 16, 1960.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR CONGRESSMAN HARRIS: This is in further reference to the Department's statement of March 11, before your committee on H.R. 7624 and S. 2197, bills which would amend the Federal Food, Drug, and Cosmetic Act relating to color additives. We indicated to the committee at that time that the Department would prefer to delay making any recommendation with reference to the so-called anticancer clause until there had been opportunity to consider the matter further.

We now understand from consultations with representatives of the Department of Health, Education, and Welfare that your committee may wish to consider also the feasibility of amendments to the Food Additives Amendment of 1958, which we understand are being sent to the committee by that Department. Accordingly, we are also commenting on these amendments in this letter.

In the passage of the original Meat Inspection and Food and Drug Acts, the Congress provided for the surveillance of all foods in interstate and foreign commerce.

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In the case of meat, a comprehensive inspection system was established with provisions for preclearance in the form of inspection of all carcasses, meats, and meat food products, including approval or rejection of chemicals and other additives. This is done under regulations issued by the Secretary of Agriculture as circumstances and the advance of knowledge require, to assure that the products marked "Inspected and Passed" are sound, healthful, wholesome, fit for human food, and truthfully labeled.

In regard to other foods, covered under the original Food and Drug Act, authority was not given for preclearance, but broad authority was established for action against foods found in interstate or foreign commerce to be in any way adulterated or misbranded.

In recent years, the trend in the Congress has been toward more preclearance in order to serve two purposes: (1) To give greater assurance of safety to the consumer; and (2) to give producers, processors, and distributors more precise guidelines for their operations in order to assure the safety of foods to consumers. Five congressional enactments are in point:

(*a*) The "new drugs" provisions of the Food, Drug, and Cosmetic Act of 1938 provided for the preclearance of drugs not generally recognized among experts qualified by scientific training and experience as safe for use under the conditions recommended.

(*b*) The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 provided for USDA preexamination of economic poisons including labeling to insure safety and effectiveness in use.

(*c*) The "Miller amendment" to the Food, Drug, and Cosmetic Act in 1954 provided more workable procedures for HEW preclearance of pesticide chemicals in or on raw agricultural commodities by authorizing the establishment of tolerances when needed—legal levels—of such chemicals in these products. The directions for use on labels registered by USDA for pesticides are gaged to meet such tolerances in or on the raw agricultural commodities.

(*d*) The Poultry Products Inspection Act of 1957 provided for extension of the meat inspection type of preclearance to poultry products by USDA.

(*e*) The Food Additives Amendment of 1958 to the Food, Drug, and Cosmetic Act provided for preclearance of chemicals and other additives to foods.

In each case the Congress provided the mechanism which permits the exercise of scientific and professional judgment in arriving at determinations of safety of use and wholesomeness of the products. These are good provisions. This Department fully supports them. The legislative histories show the necessity for the exercise of such judgment to cope with the complexity of the problems and the rapidly advancing state of knowledge concerning them.

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In addition, the Department of Health, Education, and Welfare is proposing a modification of the prior sanction (grandfather) clause contained in section 201(s) of the Food, Drug, and Cosmetic Act as follows:

"The last numbered clause of section 201(s) of the Federal Food, Drug, and Cosmetic Act (which clause is redesignated as clause (4) by section 101(a) of this act) is amended by inserting in such clause, before the period, a colon and the following: '*Provided*, That, with respect to any sanction or approval granted pursuant to this Act, this clause shall be inapplicable, and the provisions of this Act (other than this clause) relating to food additives shall apply, to any such previously sanctioned or approved use of a substance if, on the basis of the information then available, the Secretary finds that, for the reasons set forth by him, there is reasonable doubt as to its safety. Except when the Secretary finds that there is an imminent hazard to public health, he shall take such action only in conformity with section 4 of the Administrative Procedure Act if such prior sanction or approval had been made public, and only after sending reasonable notice of his proposed action and the reasons therefor to any person on whose application such prior sanction or approval had been granted and any other person who had been officially advised thereof unless such personal notice is impracticable.' "

We have no objection to this proposal since it deals only with sanctions or approvals granted by the Secretary of Health, Education, and Welfare under the Food, Drug, and Cosmetic Act and would not affect the authority of this Department or the impact of actions taken by it under programs which it administers.

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

TRUE D. MORSE, *Acting Secretary*.

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1.2f (3) CONGRESSIONAL RECORD

1.2f (3) (a) VOL. 105 (1959), Aug. 24: Amended and passed

[No Relevant Discussion on Pertinent Section]

1.2f (3) (b) VOL. 106 (1960), June 25: Debated, amended and passed House, pp. 14349, 14355, 14357–14359, 14361–14362, 14378

COLOR ADDITIVE AMENDMENTS OF 1960

Mr. DELANEY. Mr. Speaker, by direction of the Committee on Rules I call up House Resolution 559 and ask for its immediate consideration.

* * * * *

The bill before us today is known as a color additive bill and will regulate the use of colors added to our daily food supply, our drugs and cosmetics.

I anticipate that from time to time there will be other bills to improve the Federal Food, Drug, and Cosmetic Act.

H.R. 7624 originated with the Department of Health, Education, and Welfare, which sent copies of it last year to both the Senate and the House. The Senate committee took the bill, deleted certain portions, and, without holding a single hearing, reported it, and it was passed without any floor debate. I am absolutely opposed to the Senate bill.

In the House, the Interstate and Foreign Commerce Committee gave the bill prolonged study and deliberation, held many public hearings, listened on three occasions to Secretary Flemming, and then unanimously reported the bill. While I do not consider this a perfect bill, I think it is the best that we can hope for at the present time, and I support it.

[p. 14349]

The present bill also shifts the burden of proof from the Government to the sponsor of a color dye and it also contains an anticancer provision.

It is vitally important for the protection of the consumer that the producer of a dye be required to test it for safety before permitting its introduction into our foods, drugs or cosmetics. The Food and Drug Administration simply does not have the facilities or the staff to test all the colors proposed for use. The Agency is now engaged in retesting coal-tar dyes it cleared for use many years ago, and as a result of new and more sensitive testing procedures, a number of these dyes have been found to be harmful and have been removed from the approved list. FDA figures that it would take 20 years to complete the retesting program. During that time the public would have to run the risk of daily exposure to dyes which have not been clearly proven to be safe. This cannot be justified on any grounds.

[p. 14350]

Mr. ALLEN.

* * * * *

If I may be so bold as to make some suggestions, after following the learned man on this subject, the gentleman from New York. [Mr. DELANEY], I am convinced that the Senate bill, as passed, is a better bill. I am not saying it on my own authority, but I am saying it on the authority of many chemists within and without the Government.

* * * * *

While I am in sympathy with the purposes of this bill, I, after most careful consideration, favor S. 2197 as passed by the other body.

In my opinion the anticancer clause in H.R. 7624, is unnecessary and restrictive.

I also believe that the decision on safety be determined by the Secretary of Health, Education, and Welfare rather than be determined by law. Otherwise, I am certain that our court calendars presently loaded with pending cases in other fields will be even more crowded. After all why should not the Health, Education, and Welfare Department, with firsthand scientific information, decide as to safety.

It is my sincere hope that when in

conference that these two defective provisions be changed. Better still, the bill presently before us should be amended accordingly.

* * * * *

There are many chemists within and without the Government whose judgment is that the decision on safety should be determined by the Secretary of Health, Education, and Welfare rather than be determined by law.

Mr. DELANEY. Under the provision of this bill, that is the case.

Mr. ALLEN. No, that is not my understanding.

Mr. DELANEY. We are talking of the color provisions now and, as I read the bill here it is within his discretion.

Mr. ALLEN.That is not my understanding and I have a letter from some very reliable people that I have very recently received.

Mr. DELANEY. If the gentleman is talking of the food additives provision, the Secretary can determine that.

Mr. ALLEN. So I say, Mr. Speaker, that with these two things, particularly the latter part, if the Secretary of Health, Education, and Welfare does not make the decision and if it must be decided according to the law, then you are going to have more legislation in the Federal courts than you have now, and we all know that the courts are pretty crowded now.

[p. 14351]

Mr. HARRIS. Mr. Speaker, I ask unanimous consent that the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions—including maximum tolerances—under which such additives may be safely used, be considered in the House as in Committee of the Whole.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

The SPEAKER pro tempore. The Clerk will report the bill.

[p. 14352]

Mr. HARRIS. Mr. Speaker, I ask unanimous consent that the bill be printed in the RECORD showing the amendments.

The SPEAKER. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

(The bill, as amended, reads as follows:)

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this act may be cited as the "Color Additive Amendments of 1960."

TITLE I—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Definitions

SEC. 101. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended as follows:

(a) Paragraph (s) of such section (defining the term "food additive") is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

"(3) a color additive; or".

(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

"(u) The term 'safe', as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal."

(c) There is inserted, immediately after paragraph (s) of such section, the following new paragraph:

"(t) (1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays.

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

Colors or colored articles—when deemed to be adulterated or misbranded foods, drugs, or cosmetics

Food

SEC. 102. (a) (1) Clause (2) (A) of section 402(a), as amended, of such act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive."

(2) Section 402(c), as amended, of such act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(3) Section 403 of such act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Drugs

(b)(1) Clause (4) of section 501(a) of such act (relating to drugs deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows: "(4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a)."

(2) Section 502 of such Act (relating to the circumstances under which drugs are deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Cosmetics

(c)(1) Section 601(e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by adding at the end thereof the following new paragraph:

"(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a))."

Regulations to assure safety of color additives for foods, drugs, and cosmetics

SEC. 103. (a) Such Act is further amended by—

(1) repealing subsection (b) of section 406 and striking out the subsection designation "(a)" after "SEC. 406." in such section;

(2) repealing section 504;

[p. 14353]

(3) repealing section 604; and

(4) amending section 701(e) by (A) striking out "406 (a) or (b)" and inserting in lieu thereof "406"; (B) striking out "504, or 604"; and (C) inserting the word "or" after "501 (b),".

(b) Section 706 of such Act is amended to read as follows:

"Listing and certification of color additives for foods, drugs, and cosmetics

"When Color Additives Deemed Unsafe

"SEC. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a) (4), or section 601(e), as the case may be, unless—

"(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

"(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

"Listing of Colors

"(b)(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

"(2)(A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

"(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

"(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

"(5)(A) In determining for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

"(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive,

"(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

"(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

"(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

"(C)(i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) or section 701(e)) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

"(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

(iii) Where—

"(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

"(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

"(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

[p. 14354]

"(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

"(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

"(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

"(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

"Certification of Colors

"(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

"Procedure for Issuance, Amendment, or Repeal of Regulations

"(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b)(5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

"(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

"(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006 (c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

"(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409 (f)(2); and

"(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

"Fees

"(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

"Exemptions

"(f) The Secretary shall by regulation (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

Confidentiality of trade secrets

SEC. 104. Section 301(*j*), as amended, of such Act, prohibiting disclosure of trade secrets, is amended by striking out "or 704" and inserting in lieu thereof "704, or 706".

Changes in cross-reference and terminology

SEC. 105. Such Act is further amended by—

(a) striking out, in section 301(i) thereof relating to forgery or unauthorized use of certain identification devices), "404, 406(b), 504, 506, 507, or 604", and inserting in lieu thereof "404, 506, 507, or 706";

(b) (1) striking out, in clause (3) of section 303(c) (relating to color manufacturer's guarantee), the word "coal-tar" wherever it appears in such clause, and (2) inserting after the word "color", wherever it appears in such clause, the word "additive"; and

(c) striking out "harmless coloring" in section 402(d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Definitions

SEC. 201. As used in this title, the term "basic Act" means the Federal Food, Drug, and Cosmetic Act; the term "enactment date" means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

Effective date

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

Provisional listings of commercially established colors

SEC. 203. (a)(1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

(2) For the purposes of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

(b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date, and

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date, was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

[p. 14355]

Mr. HARRIS.

* * * * *

GENERAL SUMMARY

In brief, the committee bill, first, takes color additives out of the scope of the food additives amendment of 1958; second, repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); third, enacts new, integrated provisions for the separate listing of suitable color additives, safe for use in food, drugs or cosmetics, under such conditions—including tolerance limitations—as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted; fourth, provides for the certification (or exemption from certification) of listed color additives for such permitted uses; fifth, adapts the adulteration and other provisions of the

Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above-mentioned changes; and sixth, contains transitional provisions for commercially established colors.

* * * * *

So-called coal-tar colors are regulated under the act through similar sets of provisions in chapters IV Food, V Drugs, and VI Cosmetics. The act requires the Secretary of Health, Education, and Welfare to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, and cosmetics.

Food containing coal-tar color is deemed adulterated under section 402 (c) of the act unless the color is from a batch certified by the Secretary under section 406. Section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food to provide for certifying batches of such colors.

* * * * *

The Secretary of Health, Education, and Welfare is without authority to admit a coal-tar color to listing under tolerance limitations; it must be harmless per se in order for the Secretary to admit it to listing—*Flemming* v. *Florida Citrus Exchange* (358 U.S. 153 (1958)).

* * * * *

Under section 409 the food additive is deemed unsafe unless it and its use, or intended use, conform to a regulation issued by the Secretary announcing the conditions, including the establishment of tolerance limitations, under which the additive may be safely used. Food colors which were in commercial use before January 1, 1958, are allowed a grace period not later than March 6, 1961, for compliance with the provisions of the Food Additives Amendment of 1958. Such "food additive" colors, however, are not subject to any requirement of "batch" certification.

NEED FOR LEGISLATION

The principal reasons which give rise to the need for this legislation may be summarized as follows:

First. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection, in that it does not allow the Secretary of Health, Education, and Welfare to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, the Secretary must ban the use of such a color completely, as not being harmless, if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe. For externally applied drugs and cosmetics, the same principle applies if toxicity appears in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use may be wholly safe.

Prior to delisting proceedings by the Department of Health, Education, and Welfare there were 19 colors listed for unrestricted use in food, drugs, and cosmetics, 69 colors listed for unrestricted use in drugs and cosmetics, and 30 colors listed for use only in externally applied drugs and cosmetics, a total of 118 straight colors listed for certification. Seven colors have been removed from the food, drug, and cosmetic list and have been relisted for external use in drugs and cosmetic colors, so that we now have 12 food, drug, and cosmetic colors, 69 unrestricted drug and cosmetic colors, and 37 drug and cosmetic colors for external use. The Department has proposed that other colors be removed from listing and certification.

Only last week the Food and Drug Administration announced a tentative decision removing 14 coal-tar colors used principally in lipsticks from the list of permitted colors for unrestricted use in drugs and cosmetics. This decision was based upon an evaluation of evidence presented at a public hearing granted color, lipstick, and drug manufacturers. A final decision on delisting will be made after consideration of any objections which may be filed by the affected parties to the proposed order.

The principle of allowing colors to be used under tolerance limitations was endorsed, in 1956, by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program of the Food and Drug Administration, as indicated by the following excerpt from the committee's report:

> This committee feels compelled to indicate that certification of a compound as harmless and suitable for use in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified (report of the National Academy of Sciences-National Research Council Ad Hoc Advisory Committee To Review the Food and Drug Administration's Research Program on Coal-tar Dyes, June 1956).

Second. The theoretically perfect public health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While theoretically, only harmless colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many of the so-called coal-tar colors on the list may in fact be toxic in some concentrations. Yet, the Secretary of Health, Education, and Welfare cannot take a particular color off the list until he establishes its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the established colors would have to be completed—primarily by industry—and during which the Secretary could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

Third. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present there are no provisions for the certification of non-coal-tar colors. There is, moreover, no pretesting requirement for non-coal-tar additives as such, other than food additives.

Fourth. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists un-

[p. 14357]

der the present inflexible provisions of the law. Unless the law, by permitting the testing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use—including tolerance limitations and certification requirements—established by the Department of Health, Education, and Welfare.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress in temporary emergency legislation — Public Law 86-2—with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring mature oranges, after previous adoption of the "Safe-for-use" principle in the Food Additives Amendment of 1958—Public Law 85-929. In reporting upon the emergency legislation for citrus red No. 2, this committee said:

> It is specifically provided that the provisions of this bill will become inoperative on August 31, 1961, or before that time if general legislation affecting coloring materials for food is enacted by the Congress. The reason for the time limit is that this emergency legislation, which will meet the immediate needs of the citrus industry without permanently engrafting on the basic Food, Drug, and Cosmetic Act a new principle of tolerances for coal-tar colors which is not applicable to foods generally. The expiration date has been so fixed as to allow the Congress ample time to consider the application of this principle to all foods.
>
> It is the intention of the committee as soon as feasible to study amendments to the Federal Food, Drug, and Cosmetic Act dealing with color additives generally, since the need for such legislation has been amply demonstrated to this committee (86th Cong., 1st sess., H. Rept. 88).

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

EXPLANATION OF COMMITTEE BILL

The bill would change existing law in the following major respects:

First. Uniform criteria of admissibility. It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics—other than hair dyes. This would be accomplished by excepting color additives—as defined in the bill—from the term "food additive"; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section—section 706—comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification—or exemption from certification—and making other amendments to the act to mesh with these provisions.

The bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term "coal-tar color." The bill would therefore establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. The lack of consumer protection inherent in the absence of such a requirement was forcefully brought to the attention of Congress by the investigations and recommendations of the House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, the Delaney committee in the 82d Congress, and by the hearings culminating in the enactment of the Food Additives Amendment of 1958.

Second. Safety-of-use principle. The bill adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use (including maximum tolerance limitations) as are determined to be necessary to assure the safety of such use.

Third. The Delaney anticancer clause. One provision of the bill which aroused considerable controversy in the hearings on this legislation is proposed section 706(b)(5)(B) appearing on page 11, line 8, of the reported bill, and often referred to as the Delaney anticancer clause.

This clause provides that a color additive shall be deemed unsafe and shall not be listed for any use which will or may result in ingestion of all or any part of such additive if the additive is found to induce cancer when ingested by man or animal, or if it is found to induce cancer in man or animal by other tests, not involving ingestion, which are considered to be appropriate for the evaluation of the safety of additives for use in food.

[p. 14358]

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In view of the uncertainty surrounding the determination of safe tolerances for carcinogens, the committee decided that the Delaney anticancer provision in the reported bill should be retained without change.

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Fourth. Comprehensive lists. The bill retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors "generally recognized" by experts as safe for use. While there may have been justification in the case of the Food Additives Amendments of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—the Secretary of Health, Education, and Welfare does not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color. It may be noted, however, that a committee amendment to the bill deems a color additive to be suitable and safe for the purpose of listing for use generally in food, where there is in effect a published finding of the Department that the substance is generally recognized as safe for its intended use within the meaning of the provisions exempting such substances from the Food Additives Amendments of 1958.

Fifth. Certification and exemptions from certification. While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations defining the color's identity. The committee agrees with the Secretary of Health, Education, and Welfare, however, that authority to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color.

Sixth. Effective date and transitional provisions. The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act—that is, title I of the bill—would become effective as soon as the bill is enacted.

[p. 14359]

However, in order to allow on an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification —or exemption from certification in certain cases. The "commercially established" color additives falling under these transitional provisions are first, those coal-tar colors of which a batch or batches were actually certified prior to the date of enactment of the bill; and second, those non-coal-tar colors, and synthetic beta-carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for the protection of the public health during the period of provisional listing. The bill would permit establishment of a zero tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic except that, in the case of a coal-tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary of Health, Education, and Welfare.

* * * * *

Seventh. Deception. A witness before the committee suggested amending proposed section 706(b)(6) to add the word "harmful" before the word "deception" so as to provide that the Secretary shall not list a color additive for a proposed use if the data before him show that such proposed use would "promote harmful deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act."

The Federal Food, Drug, and Cosmetic Act prohibits, among other things, the introduction of an adulterated or misbranded food, drug, or cosmetic into interstate commerce, or the adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce, or while held for sale after interstate shipment. Furthermore, the food additives amendment—section 409(c)(3)(B) of the act—specifically prohibits the Secretary from issuing a regulation prescribing the conditions under which a food additive may be safely used if a fair evaluation of the data before him shows that the proposed use of the additive would "promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act."

The committee is of the opinion that it would be unsound policy to legislate against deception of the consumer in the food additives law and against harmful deception of the consumer in the color additives law. Obviously, the provision against deception of the consumer should be identical under both sections of the law. It should be emphasized that we are dealing here solely with deception which would violate the law.

[p. 14361]

Mr. SULLIVAN.

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For instance, the Secretary of Health, Education, and Welfare made a strong request to the committee for an amendment on this bill to cover a serious loophole in the Food Additives Act of 1958. The Secretary explained how that loophole got into the act—because the Department apparently made a too-sweeping statement in some of the language which it drafted for the Food Additives Act several years ago. As a result, any food additive which was ever cleared by any Government agency as being safe for the use intended, now has what amounts to an unjustified "grandfather's clause" protecting it from removal action unless the Government has proof of its danger. This is an intolerable interpretation of what Congress intended. The committee, however, has failed to recommend the repeal or modification of this language in the 1958 act, even though this provision has been causing great difficulty and, in the case of the stilbestrol-treated chickens, could be handled only through voluntary agreement at a cost of many millions of dollars to the Federal Treasury and the taxpayers.

The committee states in its report on H.R. 7624 that it is not recommending amendment of the Food Additives Act of 1958 in the color legislation because it did not consider such amendments directly germane to the color bill. It said it would consider such amendments at a later date—presumably in the next Congress. I think this is a much more serious problem, however, than the coal-tar color problem.

* * * * *

I cannot support a bill which weakens our consumer protections for the economic benefit of manufacturers using coloring material which is not completely safe. I particularly cannot support such weakening of our consumer laws, when we are not taking any steps at the same time to close glaring loopholes in the Food, Drug, and Cosmetics Act.

[p. 14369]

The bill was ordered to be read a third time, was read the third time, and passed.

A motion to reconsider was laid on the table.

The proceedings whereby H.R. 7624 was passed were vacated and that bill was laid on the table.

[p. 14378]

1.2f (3) (c) VOL. 106 (1960), June 30: Senate concurs in House amendments, pp. 15133–15137

[No Relevant Discussion on Pertinent Section]

1.2g ADMINISTRATIVE AGENCY PROCEEDINGS ACT, AUGUST 28, 1958, P.L. 85–791, §20, 72 STAT. 947

SEC. 20. (a) The first and second sentences of paragraph (2) of subsection (i) of section 408 of the Federal Food, Drug, and Cosmetic Act, as added by the Act of July 22, 1954 (ch. 559, 68 Stat. 515), are amended to read as follows:

[p. 947]

"(2) In the case of a petition with respect to an order under subsection (d) (5) or (e), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part."

(b) The first and second sentences of paragraph (3) of subsection (i) of section 408 of the Federal Food, Drug, and Cosmetic Act, as added by the Act of July 22, 1954 (ch. 559, 68 Stat. 515), are amended to read as follows:

"(3) In the case of a petition with respect to an order under subsection (l), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary of Agriculture, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part."

SEC. 21. (a) The second and third sentences of paragraph (1) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended, are amended to read as follows: "A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code."

(b) The first sentence of paragraph (3) of subsection (f) of section 701 of the Federal Food, Drug and Cosmetic Act (52 Stat. 1055), as amended, is amended to read as follows: "Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently."

SEC. 22. The second and third sentences of subsection (a) of section 10 of the Fair Labor Standards Act of 1938 (52 Stat. 1065), as amended, are amended to read as follows: "A copy of such petition shall forthwith be transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the court the record of the industry committee upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm, modify, or set aside such order in whole or in part, so far as it is applicable to the petitioner." [p. 948]

1.2g (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 842, 85th Cong., 1st Sess. (1957)

AUTHORIZING ABBREVIATED RECORDS IN REVIEWING ADMINISTRATIVE AGENCY PROCEEDINGS

JULY 23, 1957.—Ordered to be printed

Mr. WILLIS, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 6788]

The Committee on the Judiciary, to whom was referred the bill (H.R. 6788) to authorize the abbreviation of the record on the review or enforcement of orders of administrative agencies by the courts of appeals and the review or enforcement of such orders on the original papers and to make uniform the law relating to the record on review or enforcement of such orders, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill do pass.

The amendments are as follows:

* * * * * * *

PURPOSE

The purpose of the bill is to permit the several courts of appeals to adopt rules authorizing the abbreviation of the transcript and other parts of the record made before Federal administrative agencies when the orders of those agencies are to be reviewed by the courts of appeals.

In many instances much of the record made before such agencies is not relevant to the questions actually raised on appeal. This legislation, in permitting an abbreviated record to be transmitted, should result in a substantial saving of time and money without interfering with any of the appellate rights which persons now have under existing law.

[p. 6]

5. Section 21 of the bill would amend section 701 (f) of the Federal Food, Drug, and Cosmetic Act to provide in effect that the filing and contents of the administrative record with the court shall be governed by the proposed section 2112 of title 21 United States Code. We believe that, in the interest of uniformity within the Federal Food, Drug, and Cosmetic Act the additional changes contained in section 20 of the bill, above referred to, should also be incorporated in section 21. We therefore suggest that section 21 be changed to read as follows:

"SEC. 21. (a) The second and third sentences of paragraph (1) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C., 371 (f)), are amended to read as follows: 'A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code.'

"(b) The first sentence of paragraph (3) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 (f)) is amended to read as follows: 'Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently'."

[p. 21]

1.2g (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 2129, 85th Cong., 2nd Sess. (1958)

AUTHORIZING ABBREVIATED RECORDS IN REVIEWING ADMINISTRATIVE AGENCY PROCEEDINGS

AUGUST 4, 1958.—Ordered to be printed

Mr. EASTLAND, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 6788]

The Committee on the Judiciary, to which was referred the bill (H.R. 6788) to authorize the abbreviation of the record on the review or enforcement of orders of administrative agencies by the courts of appeals and the review or enforcement of such orders on the original papers and to make uniform the law relating to the record on review or enforcement of such orders, and for other purposes, having considered the same, reports favorably thereon, without amendment and recommends that the bill do pass.

PURPOSE

The purpose of the proposed legislation is to save time and expense by permitting the several courts of appeals to adopt rules authorizing the abbreviation of the transcript and other parts of the record made before Federal administrative agencies when the orders of those agencies are to be reviewed by the courts of appeals. If review proceedings have been instituted in two or more courts with respect to the same order, the bill would require the Federal administrative agency involved to file the record in that court in which the proceeding was first instituted, but in the interest of justice and for the convenience of the parties, such court may thereafter transfer the proceedings to another court of appeals.

[p. 1]

STATEMENT

1. ORIGIN AND PRIOR CONSIDERATION

This proposal emanates from the Judicial Conference of the United States. It was submitted to the Congress after substantial consideration by the Committee on Revision of the Laws of the Judicial Conference and the Judicial Conference itself. After submission, it was the subject of a hearing before a subcommittee of the House Committee on the Judiciary on May 17, 1956, and subjected to agency comments. It was thereafter revised and reintroduced and again subjected to review by the administrative agencies. Following this, the Judiciary Committee after adopting several amendments, reported the bill to the House of Representatives, which later approved it.

The bill has been approved in principle by the American Bar Association, and it incorporates a recommendation of the President's Conference on Administrative Procedure. It likewise carries the approval of the Judicial Conference of the United States.

2. DISCUSSION AND SUMMARY

Most of the present statutes which provide for judicial review or enforcement by the courts of appeals of the orders of administrative agencies require that a transcript of the entire record of the proceedings before the agency be prepared by the agency and physically filed with the court. Such a requirement frequently operates to delay court proceedings and to impose upon the agency large and unnecessary expenditures of money and effort. In many types of cases the agency record involves persons other than the petitioner for review. The record may, therefore, be unnecessarily voluminous and much of it irrelevant to the review.

The object of the instant legislation is to eliminate the filing of the entire record except in those instances where it is required for an adequate determination or where the abbreviation of the record would prove more costly than the transmission of the entire record. This objective could have been accomplished by a general statute repealing all inconsistent provisions of the various acts providing for judicial review of agency action. Such a course, however, would have left residuum of doubt as to whether specific provisions would have been repealed by implication. This legislation avoids that difficulty by direct amendment of the many existing statutes providing for judicial review of administrative determinations and orders.

[p. 2]

CONCLUSION

With the advent of an increasing number of bureaus and agencies within the Federal Government, the Congress has seen fit to authorize judicial review of the orders of such agencies and bureaus in order to afford maximum protection to the interests of the Government and the individual or corporate litigant. In many cases this review function has been placed upon the Federal courts of appeals, thereby increasing the workload of that part of the Federal court system. Part of that workload involves the perusal of records filed in connection with such appeals. These records are frequently voluminous and are not edited, so as to encompass only information relevant to the points at issue. The reduction of such a record to its pertinent parts, as proposed here, should in most cases serve as an aid to the expedition of appeals from orders of administrative agencies. Thus, adoption of this measure is expected to facilitate the work of the Federal appellate courts. Moreover, this legislation is likewise expected to occasion a saving in time and expense to the Federal Government in its role as litigant. The cost of preparing the transcript in nearly all cases rests with the agency and is, therefore, a charge upon the Federal Treasury. Consequently, any reduction in the size of the record which must be filed could result in reducing the cost of litigation to the Government.

In addition to these considerations, the authority conferred by the bill contains sufficient flexibility to permit an appellate court to adapt its procedures to the exigencies of cases presented to it. Thus, if a litigant, either an individual or an agency, determined that the cause of justice, or considerations of time or expense, require the submission of a full record, that may be done. The purpose of the proposal is expedition, but not expedition at the expense of justice.

[p. 4]

SEC. 21. (a) The second and third sentences of paragraph (1) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended: *A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose.* [The summons and petition may be served at any place in the United States.] The Secretary [promptly upon service of the summons and petition] *thereupon* shall [certify and] file in the court the [transcript] *record* of the proceedings [and the record] on which the Secretary based his order, *as provided in section 2112 of title 28, United States Code.*"

(b) The first sentence of paragraph 3 of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended: "*Upon the filing of the petition referred to in paragraph (1) of this subsection, the* [The] court shall have jurisdiction to affirm the order, or to set aside in whole or in part, temporarily or permanently." (21 U.S.C., sec. 371, Secretary of Health, Education, and Welfare.)

[p. 17]

1.2g (3) CONGRESSIONAL RECORD

1.2g (3) (a) Vol. 103 (1957), Aug. 5: Amended and passed House, pp. 13617–13621

[No Relevant Discussion on Pertinent Section]

1.2g (3) (b) Vol. 104 (1958), Aug. 14: Passed Senate, p. 17537

[No Relevant Discussion on Pertinent Section]

1.2h AMENDMENTS TO FOOD ADDITIVES JUNE 29, 1960, P.L. 86–546, 74 STAT. 255

AN ACT

To make the uniform law relating to the record on review of agency orders (Public Law 85–791) applicable to the judicial review of orders issued under the Federal Aviation Act of 1958 and the Food Additives Amendment of 1958.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That subsection (c) of section 1006 of the Federal Aviation Act of 1958 (72 Stat. 795) is amended to read as follows:

"(c) A copy of the petition shall, upon filing, be forthwith transmitted to the Board or Administrator by the clerk of the court, and the Board or Administrator shall thereupon file in the court the record, if any, upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code."

SEC. 2. The first and second sentences of paragraph (2) of subsection (g) of section 409 of the Federal Food, Drug, and Cosmetic Act, as added by the Food Additives Amendment of 1958 (72 Stat. 1788), are amended to read as follows: "A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order."

Approved June 29, 1960.

1.2h (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 1462, 86th Cong., 2d Sess. (1960)

REVIEW OF CERTAIN AGENCY ORDERS

APRIL 7, 1960.—Referred to the House Calendar and ordered to be printed

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Mr. WILLIS, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 7847]

The Committee on the Judiciary, to whom was referred the bill (H.R. 7847) to make the uniform law relating to the record on review of agency orders (Public Law 85–791) applicable to the judicial review of orders issued under the Federal Aviation Act of 1958 and the Food Additives Amendment of 1958, having considered the same, report favorably thereon with amendment and recommend that the bill do pass.

The amendment is as follows:

On page 2, line 12, strike out the last sentence and insert in lieu thereof the following:

> Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order.

EXPLANATION OF AMENDMENT

To bring the pertinent part of section 2 of the bill into line with the provisions of present law (21 U.S.C. 348(g)(2)) which give the court exclusive jurisdiction upon the filing of the transcript of the record and not, as set forth in the bill as introduced, upon the filing of the petition.

PURPOSE

The purpose of this legislation is to bring judicial review provisions of the Federal Aviation Act of 1958 and the Food Additives Amendment of 1958 under the uniform provisions of Public Law 85–791 relating to court review of Government agency orders.

[p. 1]

ANALYSIS OF THE BILL

* * * * * * *

Section 2 of the bill provides that appeals under section 409 of the Federal Food, Drug, and Cosmetic Act, as amended, taken from agency orders shall be accomplished by filing a petition with the court. The clerk of the court shall forthwith transmit to the Secretary of Health, Education, and Welfare, or his designee, a copy of the petition, and upon receipt thereof the Secretary shall file in the court the record of the proceedings upon which the order complained of is based, in accordance with provisions of section 2112 title 28, United States Code. Upon the filing of such petition the court has jurisdiction which, upon the filing of the record, becomes exclusive to affirm or set aside the order complained of. Until the filing of the record, however, the Secretary may modify or set aside his order.

The committee wishes to make clear that the provision of the last sentence of the amended bill, which gives the court exclusive jurisdiction upon the filing of the record, is not intended to modify the application of the provisions of 28 U.S.C. 2112 that determines which single court of appeals has jurisdiction where proceedings to review the same agency order are instituted in two or more courts of appeals.

[p. 6]

CHANGES IN EXISTING LAW

In compliance with clause 3 of rule XIII of the House of Representatives, there is printed below in roman existing law in which no change is proposed, with matter proposed to be stricken out enclosed in black brackets, and new matter proposed to be added shown in italic:

72 Stat. 795; 49 U.S.C. 1486

JUDICIAL REVIEW OF ORDERS

ORDERS OF BOARD AND ADMINISTRATOR SUBJECT TO REVIEW

SEC. 1006. (a) * * *

(b) * * *

(c) Notice to Board or Administrator; filing of transcript.

[A copy of the petition shall, upon filing be forthwith transmitted to the Board or Administrator by the clerk of the Court, and the Board or Administrator shall thereupon certify and file in the court a transcript of the record, if any, upon which the order complained of was entered.]

A copy of the petition shall, upon filing, be forthwith transmitted to the Board or Administrator by the clerk of the court, and the Board or Administrator shall thereupon file in the court the record, if any, upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code.

72 Stat. 1788; 21 U.S.C. 348g (2)

SEC. 409.

(g) Judicial review.

(1) * * *

(2) [A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part.]

***A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order.* * * ***

[p. 8]

1.2h (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 1566, 86th Cong., 2d Sess. (1960)

[No Relevant Discussion]

1.2h (3) CONGRESSIONAL RECORD, VOL. 106 (1960)

1.2h (3) (a) April 19: Amended and passed House, p. 8190

[No Relevant Discussion on Pertinent Section]

1.2h (3) (b) June 18: Passed Senate, p. 13203

[No Relevant Discussion on Pertinent Section]

1.2i DRUG AMENDMENTS OF 1962, OCTOBER 10, 1962, P.L. 87-781, TITLE I, SECTION 104(f) (1), 76 Stat. 785

SEC. 104.

* * * * * * *

(f) (1) Clause (A) of paragraph (3) of section 409 (c) of such Act (21 U.S.C. 348 (c)) is amended by inserting before the semicolon at the end thereof the following: ", except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of

use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal".

(2) Subparagraph (B) of paragraph (5) of section 706 (b) of such Act (21 U.S.C. 376 (b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: "*Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

[p. 785]

1.2i (1) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 1744 (part 1 & 2), 87th Cong., 2d. Sess. (1962)

DRUG INDUSTRY ACT OF 1962

JULY 19, 1962.—Ordered to be printed

Mr. EASTLAND, from the Committee on the Judiciary, submitted the following

REPORT

together with

INDIVIDUAL VIEWS

[To accompany S. 1552]

The Committee on the Judiciary, to which was referred the bill (S. 1552) to amend and supplement the antitrust laws with respect to the manufacture and distribution of drugs, and for other purposes, having considered the same, reports favorably thereon, with an amendment in the nature of a substitute, and recommends that the bill, as amended, do pass.

AMENDMENT

Strike all after the enacting clause and insert in lieu thereof the following:

That this Act may be cited as the "Drug Industry Act of 1962".

[No Relevant Discussion on Pertinent Section]

[p. 1]

1.2i (2) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 2464, 87th Cong., 2d Sess. (1962)

DRUG AMENDMENTS OF 1962

SEPTEMBER 22, 1962.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. HARRIS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 11581]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 11581) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are as follows:

The amendment to the text strikes out all of the bill after the enacting clause and inserts in lieu thereof a substitute which appears in the reported bill in italic type. The substitute text is also printed in appendix C.

The other amendment modifies the title of the bill to make it conform to the changes made by the amendment to the text.

[p. 1]

ANIMAL FEED

The committee amended the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal.

[p. 5]

COMMITTEE HEARINGS

The committee held extensive hearings on June 19–22, 1962, on H.R. 11581 and H.R. 11582 and on August 20–23, 1962, on H.R. 11581. Both of these bills were introduced by Chairman Harris at the request of the Department of Health, Education, and Welfare to give effect to a part of the President's message on consumer protection.

H.R. 11581 seeks to amend the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs; authorize standardization of drug names; establish special controls for barbiturate and stimulant drugs; and clarify and strengthen existing inspection authority with respect to any articles subject to the act.

H.R. 11582 seeks to amend this act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices; and amend the act with respect to cautionary labeling.

[p. 6]

Lack of time prevented further committee consideration of the bill, H.R. 11582, and it is expected that this legislation will be considered further during the next Congress.

While the committee had under consideration H.R. 11581, there was referred to the committee a Senate passed pill, S. 1552. The Senate bill deals in a somewhat different manner with several of the aspects covered by H.R. 11581.

The committee in executive session considered the provisions both of H.R. 11581 and S. 1552. The committee amendment in the nature of a substitute takes the place of both of these bills.

The committee amendment omits provisions relating to the control of barbiturates and stimulant drugs and biological drugs which were contained in H.R. 11581. The committee expects to give careful consideration to these provisions during the next Congress.

AGENCY REPORTS

Agency reports relating to H.R. 11581 are shown in appendix A to this report.

SECTION-BY-SECTION ANALYSIS OF BILL

SHORT TITLE

The first section of the bill would provide that the act may be cited as the "Drug Amendments of 1962."

[p. 7]

Section 104(f) amends sections 409(c) and 706(d) of the Federal Food, Drug, and Cosmetic Act, by making the anticancer clause of the Food Additives Amendment of 1958 and the Color Additive Amendment of 1960 inapplicable to chemicals, such as veterinary drugs, when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food, such as milk or eggs, yielded by or derived from the living animal.

[p. 11]

1.2i (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 2526, 87th Cong., 2d Sess. (1962)

DRUG AMENDMENTS OF 1962

OCTOBER 3, 1962.—Ordered to be printed

Mr. ROBERTS of Alabama, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 1552]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 1552) to amend and supplement the laws with respect to the manufacture and distribution of drugs, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Drug Amendments of 1962".

TABLE OF CONTENTS

TITLE I—DRUGS

PART A—AMENDMENTS TO ASSURE SAFETY, EFFECTIVENESS, AND RELIABILITY

Sec. 101. Requirement of adequate controls in manufacture.
Sec. 102. Effectiveness and safety of new drugs.
Sec. 103. Records and reports as to experience on new drugs.
Sec. 104. New drug clearance procedure.
Sec. 105. Certification of antibiotics
Sec. 106. Records and reports as to experience on antibiotics.
Sec. 107. Effective dates and application of part A.

PART B—STANDARDIZATION OF DRUG NAMES

Sec. 111. Review and designation of official names.
Sec. 112. Name to be used on drug label.
Sec. 113. Exclusion of cosmetics.
Sec. 114. Information to physicians.

[p. 1]

PART C—AMENDMENTS AS TO ADVERTISING

Sec. 131. Prescription drug advertisements.

TITLE II—FACTORY INSPECTION AND EFFECT ON STATE LAWS

Sec. 201. Factory inspection.
Sec. 202. Effective on State laws.
Sec. 203. Effective date.

TITLE III—REGISTRATION OF DRUG ESTABLISHMENTS AND PATENT INFORMATION

Sec. 301. Findings and declaration.
Sec. 302. Registration of producers of drugs.
Sec. 303. Transitional provisions.
Sec. 304. Failure to register.
Sec. 305. Drugs from nonregistered establishments misbranded.
Sec. 306. Samples of imported drugs.
Sec. 307. Definitions.
Sec. 308. Information on patents for drugs.

[p. 2]

NEW DRUG CLEARANCE PROCEDURE

Sec. 104. (a) Section 505 (a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (a)), is amended to read as follows:

* * * * * * *

[p. 5]

(f)(1) Clause (A) of paragraph (3) of section 409(c) of such Act (21 U.S.C. 348 (c)) is amended by inserting before the semicolon at the end thereof the following: ", except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal".

[p. 6]

(2) Subparagraph (B) of paragraph (5) of section 706(b) of such Act (21 U.S.C. 376(b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: "Provided, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

[p. 7]

And the House agree to the same.

That the Senate recede from its disagreement to the amendment of the House to the title and agree to the same.

OREN HARRIS,
KENNETH A. ROBERTS,
LEO W. O'BRIEN,
PAUL G. ROGERS,
JOHN B. BENNETT,
PAUL F. SCHENCK,
ANCHER NELSEN,
Managers on the Part of the House.

JAMES O. EASTLAND,
ESTES KEFAUVER,
OLIN D. JOHNSTON,
EVERETT M. DIRKSEN,
ROMAN L. HRUSKA,
Managers on the Part of the Senate.

[p. 18]

STATEMENT OF THE MANAGERS ON THE PART OF THE HOUSE

The managers on the part of the House at the conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 1552) to amend and supplement the laws with respect to the manufacture and distribution of drugs, and for other purposes, submit the following statement in explanation of the effect of the action agreed upon by the conferees and recommended in the accompanying conference report:

The House struck out all of the Senate bill after the enacting clause and inserted a substitute amendment.

The committee of conference has agreed to a substitute for both the Senate bill and the House amendment. Except for clarifying, clerical, and conforming changes, the differences are noted below:

[p. 19]

* * * * * * *

ANIMAL FEED

The House amendment contained a provision amending the anticancer clause of the food additives amendment and the color [p. 20] additive amendment of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal.

The Senate bill did not contain this provision.

The conference substitute adopts the House provision in this respect.

[p. 21]

DEFINITION

The Senate bill contained a definition of the term "State." The House amendment did not contain any such definition.

The conference report defines "State" appropriately for the different sections of the act and revises the definition of the term "Territory" to exclude the Commonwealth of Puerto Rico.

OREN HARRIS,
KENNETH A. ROBERTS,
LEO W. O'BRIEN,
PAUL G. ROGERS,
JOHN B. BENNETT,
PAUL F. SCHENCK,
ANCHER NELSEN,
Managers on the Part of the House.

[p. 27]

1.2i (4) CONGRESSIONAL RECORD, VOL. 108 (1962)

1.2i (4) (a) Aug. 23: Debated, amended, and passed Senate, pp. 17364–17422

[No Relevant Discussion on Pertinent Section]

1.2i (4) (b) Sept. 27: Amended and Passed House, pp. 21092, 21096–21097, 21099–21100

Mr. HARRIS. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the Senate bill (S. 1552) to amend and supplement the laws with respect to the manufacture and distribution of drugs, and for other purposes, strike out all after the enacting clause, and insert in lieu thereof the provisions of H.R. 11581, to protect the public health by amending the Federal Food, Drug and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws, just passed.

[p. 21092]

The SPEAKER. The Clerk will report the amendment.

The Clerk read as follows:

Amendment offered by Mr. Harris: strike out all after the enacting clause and insert the following:

[p. 21096]

* * * * *

"New Drug Clearance Procedure

"SEC. 104. (a) Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)), is amended to read as follows:

* * * * *

"(f)(1) Clause (A) of paragraph (3) of section 409(c) of such Act (21 U.S.C. 348(c)) is amended by inserting before the semicolon at the end thereof the following: ', except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal'.

"(2) Subparagraph (B) of paragraph (5) of section 706(b) of such Act (21 U.S.C. 376(b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: '*Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal'.

[p. 21097]

The amendment was agreed to.

[p. 21099]

The Senate bill was ordered to be read a third time, was read the third time and passed.

A motion to reconsider was laid on the table.

The title was amended so as to read: "An Act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority, and for other purposes."

Mr. HARRIS. Mr. Speaker, I move that the House insist upon the provisions of the bill passed by the House and request a conference with the Senate.

The motion was agreed to.

The SPEAKER. The Chair appoints the following conferees: Messrs. HARRIS, ROBERTS of Alabama, O'BRIEN of New York, ROGERS of Florida, BENNET of Michigan, SCHENCK, and NELSEN.

[p. 21100]

1.2i (4) (c) Oct. 3: Senate agrees to conference report. pp. 22137, 22039, 22041–22042, 22044–22045, 22049, 22050

DRUG INDUSTRY ACT OF 1962—CONFERENCE REPORT

Mr. KEFAUVER. Madam President, I submit a report of the committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 1552) to amend and supplement the antitrust laws with respect to the manufacture and distribution of drugs, and for other purposes. I ask unanimous consent for the present consideration of the report.

The PRESIDING OFFICER. The report will be read for the information of the Senate.

(The legislative clerk read the report.)

(For conference report, see House

proceedings of Oct. 4, 1962, p. 22315, CONGRESSIONAL RECORD.)

The PRESIDING OFFICER. Is there objection to the present consideration of the report?

There being no objection, the Senate proceeded to consider the report.

[p. 22037]

Mr. KEFAUVER.

* * * * *

SECTION 104—NEW DRUG CLEARANCE PROCEDURE

There was only one difference between the Senate and House language with respect to the new drug clearance procedure. Both bills provided that a new drug application cannot become effective automatically under any circumstances but must be affirmatively approved. Both provided that the Secretary initially has 180 days—unless further extended by agreement — in which to decide to approve the application or to give notice of an opportunity for a hearing; that the applicant has 30 days in which to request a hearing; and that the hearing would have to begin within 90 days after such 30 days, or within a total of 120 days after notice of the opportunity of a hearing. The Senate bill did not set forth any time period by which an order would have to be entered following the hearing. The House bill required the order to be issued in 90 days after the completion of the hearing. A compromise was worked out to the effect that the order would have to be issued within 90 days, not after the hearing, but after the date fixed by the Secretary for filing final briefs. This is the last step in the hearing process prior to the final decision of the Secretary.

I personally felt that the Senate bill, which put no limit on the time that the HEW could take after the hearing, was preferable, but I trust that the present provision will be adequate.

The conferees also accepted a House provision which would correct a needless and unintentional inequity in the application of the food additive anticancer proviso to additives for animal feed, while preserving in its full vigor the consumer protection now afforded by that provision.

The provision stipulates that the anticancer proviso of existing law shall not apply with respect to the use of a substance—for example, a veterinary drug—as an ingredient of feed for animals which are raised for food production, if the Secretary finds, first, that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended; and, second, that no residue of the additive will be found in any edible portion of such animals after slaughter or in any food product of the living animal—such as milk or eggs.

Another amendment would similarly amend the basic act—which is the corresponding anticancer clause contained in the color additive amendment of 1960 to the basic act.

It should be emphasized that where a new drug is involved in these fields and subsequent information and new evidence raise a question as to its safety, it can be withdrawn under the new withdrawal and suspension powers provided for in section 102 of the bill.

SECTION 105—CERTIFICATION OF ALL ANTIBIOTICS

On this matter the conferees adopted the Senate language with, however, one important limitation contained in the House bill; namely, that the requirement for batch certification for antibiotics not included in the present law be limited to those "intended for use by man." In other words, antibiotics not now subject to certification which are solely intended for such uses as veterinary purposes, animal feed, et cetera, will not be required to go through batch-by-batch certification. They will be subject to safety and effectiveness tests under the new drug procedures including the new withdrawal powers provided in section 102.

I strongly urged that there should be batch testing of antibiotics for use by veterinarians in treating animals and in animal feed as well as those used for treating human beings, on the theory that if an impure antibiotic is used on a cow or a steer, the milk or the meat might be infected, but I could not prevail. That may be a subject of legislative consideration in the next session of Congress.

The conferees also agreed to an amendment relating to proof of effectiveness of antibiotics now on the market which have been cleared for safety through the new drug procedure of the act but have not until now been subject to batch-by-batch certification. The purpose of this amendment is to facilitate the prompt certification of those approximately 30 antibiotics that have been approved for safety only under the new drug provisions. Under the certification procedure these antibiotics will have to be both safe and effective for their intended use. In the period of transition, these antibiotics will be approved for certification for the same conditions that have been approved in their new drug application. However, the Food and Drug Administration under this amendment is empowered to review the adequacy of the evidence on effectiveness and if it concluded that there is a lack of substantial evidence to support any or all of the existing claims, it can change the certification to eliminate these unsubstantiated claims. There of course would be public procedure with an opportunity for hearings and judicial review afforded the drug manufacturers before the FDA began this type of action.

[p. 22039]

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The moral of the drug bill is that even on an exceedingly complex issue the legislative branch can perform in the manner originally intended. With only a small staff of competent professional personnel the Congress can prove itself to be just as able as the vast bureaucracy of the executive branch, if not more so, to assume leadership in the legislative process.

Madam President, I yield the floor.

The PRESIDING OFFICER (Mrs. NEUBERGER in the chair). The question is on agreeing to the conference report.

The report was agreed to.

During the delivery of Mr. KEFAUVER'S speech,

Mr. CARROLL. Madam President, will the Senator from Tennessee yield?

Mr. KEFAUVER. I yield to the Senator from Colorado, a distinguished member of the Subcommittee on Antitrust and Monopoly, who worked long and hard on the bill and whose labors we all appreciate.

Mr. CARROLL. Madam President, I desire to pay tribute to the long and arduous work of the Senator from Tennessee [Mr. KEFAUVER] and the Senator from Michigan [Mr. HART], and to the excellent work done by the staff over a period of some 3 years, led [p. 22041] by Dr. John Blair, which has led to the bill which is before the Senate today for passage. No one can really fully appreciate the scope of the bill unless he has read the record or has attended the hearings which took place through many years.

S. 1552, a bill to amend and supplement the laws with respect to the manufacture and distribution of drugs, is the result of 3 years of investigation and research undertaken by the Antitrust and Monopoly Subcommittee of which I am proud to be a member. During much of this time we of the subcommittee had very little support and many obstacles were placed in our path. It did not look as though we could obtain a meaningful bill. During all of this period, I am pleased to say that our chairman, the Senator from Tennessee, never once was dissuaded from his purpose.

As a result of the work done by our committee members and by our committee staff—and unhappily because of the great and tragic experience in Europe with the experimental drug thalidomide—we have before us today a measure which marks a major strengthening of the Federal drug controls.

I am especially pleased that the bill before the Senate, as approved by the conference committee, embodies within it the so-called Carroll-Javits amendment, which requires for patient prenotification before experimental drugs can be prescribed.

When we first presented this amendment we were told that it was not feasible. We persisted with our amendment, however, because we felt that when a man or his loved one consults his family doctor, he has the right to be assured that only safe and proven medicines will be administered.

In the Senate version of the bill, Senator JAVITS and I were successful in obtaining an amendment—not all that we sought, it is true—which would insure that patients' rights would be considered in the promulgation of regulations for the use of experimental drugs.

Fortunately, happily, the House was able to go even further in this respect with the result that the bill before us today provides that a doctor must obtain a patient's permission to be treated with an experimental drug. The only exceptions to this lie in those cases where a doctor feels obtaining such permission would not be feasible or in the patient's best interest.

Madam President, I am proud to have worked shoulder to shoulder with the Senator from Tennessee [Mr. KEFAUVER] in this endeavor. I urge the Senate to give this conference report its speedy approval.

Madam President, I ask unanimous consent to have printed at this point in the RECORD an article entitled "Conferees Vote Real Tightening Control of Drugs," published in the Wall Street Journal of today, October 3, 1962.

The PRESIDING OFFICER. Is there objection?

There being no objection, the article was ordered to be printed in the RECORD, as follows:

CONFEREES VOTE BILL TIGHTENING CONTROL OF DRUGS—COMPROMISE MAKES FIRMS REGISTER WITH AGENCY; FINAL PASSAGE LIKELY SOON—SOME KENNEDY CLAUSES EASED

Washington.—A Senate-House conference approved a bill tightening Federal controls over the manufacture and marketing of prescription drugs. Both Chambers are expected to approve the measure by tomorrow and send it to the White House.

The conferees accepted the Senate bill's requirement that drug manufacturers register with the Government and a House provision that side-effect information to be included in drug advertisements need only be "in brief summary." But they rejected a Senate proposal that the Government publish and distribute to doctors, clinics, and libraries copies of the printed material that the Government requires be included in drug packages, containing detailed information on the use and effects of the drug.

The bill's controls are not as tight as those proposed by the Kennedy administration, and the measure omits some administration provisions: New controls over barbiturates, amphetamines, and biological drugs, and authority for thorough Government inspection of factories producing nonprescription drugs.

PROVISIONS LISTED

These are the other major provisions of the bill:

Thorough Federal inspection is authorized for factories producing prescription drugs.

Drugs must be turned out under good manufacturing practices, must be safe, and meet the quality and purity characteristics claimed for them.

New drugs can't be marketed until specific approval is granted by the Food and Drug Administration, and a manufacturer must show "substantial evidence" that a new drug will have the effect claimed for it. The FDA is given 180 days in which to consider a new-drug application; an applicant has an additional 30 days to request a hearing if the FDA refuses to approve the drug; the agency has 90 days after that to hold a hearing, and the agency has 90 days after the date set for filing final legal briefs to issue a decision.

The Government may withdraw from the market any drug believed to present an "imminent hazard" to the public.

Government controls over the manufacture of certain antibiotics are extended to all of them.

Manufacturers must keep records of side effects and other experience with drugs and make these records available to the FDA.

The common or official name of a drug must be printed on the label prominently and in type at least half as large as that of the brand name. The FDA is authorized to determine a drug's official name when the industry cannot agree.

EXPERIMENTAL DRUGS

In addition to these legal requirements, the bill authorizes the FDA to include certain specified provisions in its regulations governing the use of experimental drugs, those not yet approved for general public sale. Thalidomide, the widely publicized German sleeping pill that was linked to deformities in newborn babies, was distributed in this country as such an experimental drug and was not approved by the FDA. The bill's suggested new regulations, largely similar to those proposed recently by the FDA itself, would require doctors to:

Obtain a patient's permission to be treated with an experimental drug, except when the doctor feels obtaining such permission wouldn't be feasible or in the patient's best interest.

Report to manufacturers and indirectly to the Government on the results of experimental drugs.

And administer experimental drugs only to patients under their personal supervision.

Although the bill doesn't require the FDA to issue these regulations, members of the conference committee said it assumed the agency would agree to the recommendations.

[p. 22042]

Mr. KEFAUVER. Anyway, it will all be in the RECORD. I ask unanimous consent that the minority views, beginning on page 33 of the committee report, and the comparative analysis to which the Senator from Nebraska referred may be printed in the RECORD at this point.

Mr. HRUSKA. Madam President, if the Senator will yield, the comparative analysis appears on several pages. I would prefer to have that compiled in one statement. It would be difficult to take only one page and to get the comparative analysis.

Mr. KEFAUVER. Madam President, I ask unanimous consent to have it included, when it is prepared.

Mr. HRUSKA. I thank the Senator.

Mr. KEFAUVER. And to further aid in the understanding of the legislative history, my statement of August 20, 1962.

The PRESIDING OFFICER. Is there objection to the request by the Senator from Tennessee?

There being no objection, the material was ordered to be printed in the RECORD, as follows:

VIEWS OF SENATORS ESTES KEFAUVER, JOHN A. CARROLL,[1] THOMAS J. DODD, PHILIP A. HART, AND EDWARD V. LONG

The undersigned voted to report favorably S. 1552 as rewritten by the full Judiciary Committee because it does contain some provisions which are improvements in the present law. Moreover, in view of the great interest in the subject, we felt the Senate as a whole should have the opportunity of acting on certain amendments which would strengthen the bill.

In the form in which it was originally introduced on April 12, 1961, as well as the form in which it was reported out by the Subcommittee on Antitrust and Monopoly on March 8, 1962, S. 1552 had three objectives:

1. To bring about reductions in the present high prices of drugs.
2. To provide physicians with better and more adequate information about drugs and correlatively to reduce the dissemination of information which is false and misleading.
3. To insure that all drugs are of adequate and acceptable quality.

In the form in which it was reported out by the full Judiciary Committee, S. 1552 will have only a very limited effect on prices, confined [p. 22044] to the minority of drugs which are not patented. It will also have only a very limited effect in improving the quality of information reaching physicians. Its major result will be to improve the quality of drugs.

While improvement in the quality of a product is always desirable and S. 1552 should be enacted for this purpose alone, the record is clear that by any test and under any standard the prices of most drugs are excessive and unreasonable. The record is also clear that physicians are regularly inundated with a great mass of advertising and promotional material, much of which is misleading and some actually false.

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Requiring drug plants to register their names and addresses with the FDA, granting the agency stronger inspection powers and requiring drug plants to conform to current good manufacturing practice should tend to give physicians greater confidence that, if they prescribe by official or generic names, their patients will receive drugs of adequate and acceptable quality (secs. 3, 4, and 5 of S. 1552). Similarly, the provision granting the Secretary of Health, Education, and Welfare authority under certain conditions to establish the official names should make for shorter and less complex generic names that physicians can remember, pronounce, and spell (sec. 10). Because of these changes it would be hoped that with the passage of time more and more physicians will come to prescribe by generic names. This should mean lower prices for the patients of such doctors for drugs which are not patented and are not already sold on a generic-name basis, such as phenobarbital, digitoxin, and others. The drugs in which consumers can benefit from generic-name prescribing probably represent less than a fifth of all prescription sales.

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[1] Senator CARROLL concurs in all except amendment No. 5 (see further individual views).

Likewise, only three of the nine provisions will contribute to providing physicians with better information about drugs and reducing the volume of misleading information. There is, first, the requirement that HEW publish the package inserts in convenient and readable form and distribute them to physicians (sec 11). Second is the provision authorizing the Commissioner of Patents to secure information on drugs from the Department of Health, Education, and Welfare (sec. 2). Presumably, if the Patent Office, which has no physicians or pharmacologists on its staff, is able to secure information from HEW on the therapeutic properties of drugs—which it is now able to obtain only with the consent of the patent applicant—fewer patents may be issued. This in turn should tend to reduce the number of products which could be the subject of high-pressure blitz advertising and promotional campaigns aimed at the doctors. Third is the provision requiring the keeping of records and reports on clinical testing, which should assist the FDA in keeping off the market unsafe and ineffective drugs or in prescribing proper and appropriate warnings to guide physicians in their use (sec. 7).

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[p. 22045]

AMENDMENT NO. 3—NEW DRUG CLEARANCE PROCEDURES

Under the present law a new drug application becomes effective automatically in 60 days unless it is disapproved or the Secretary postpones its effective date "to such time (not more than 180 days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the issue." Under S. 1552, as reported by the Antitrust Subcommittee, no time limit is imposed; the application would not become effective until the Secretary had determined that the drug is "safe for use and is efficacious in use under conditions prescribed, recommended, or suggested in the labeling thereof." Under the bill as reported by the Judiciary Committee the 60-day provision of the present law is extended to 90 days, and if a hearing is held, action pursuant to the hearing need not be taken within the 180-day period, as is required by regulation under the current law.

The need to give the physicians of the FDA adequate time to appraise the safety and effectiveness of drugs is dramatically illustrated by the recent case example of thalidomide. This drug, developed by the German firm, Chemie Grunenthal, was extensively sold in Western Europe, England, Canada, Brazil, Japan, and other countries as a sedative. Since it produced a deep sleep and did not have the "hangover effects" of other sedatives, it achieved great popularity and was manufactured literally by the ton. Unfortunately, it also happens to have horrible side effects. When given to expectant mothers in early pregnancy, their babies may be born with assorted malformations, particularly with a condition called phocomelia, or "seal limbs," because the hands and feet are attached close to the body like flippers, with little or no arms or legs. Medical authorities estimate that from 3,500 to 5,000 malformed babies resulting from the use of this drug will have been born in Europe by this fall.

By the fall of 1961 the incidence in Europe of these malformations, hitherto an exceedingly rare phenomenon, had reached epidemic proportions. In September 1961 four German universities set up a cooperative study which was reported at a conference on November 18, 1961. Dr. Widukind Lenz, a pediatrician with special interest in genetics, discussed the possible role of thalidomide (Contergan) in the deformity of infants called seal limbs. Drs. R. A. Pfeiffer and W. Kowenow reported a high statistical significance connecting seal limbs with thalidomide.

As the studies continued, irrefutable evidence developed. In the February 3, 1962, issue of the Lancet, Dr. Lenz wrote: "I have conclusive evidence that Contergan (thalidomide) is teratogenic (monster producing) in man." This evidence was based on studies of mothers who disclosed before delivery that they had taken thalidomide and in which the infants showed typical malformations; 55 cases in which the exact date of the prescription coincides with the time of development of the malformed organs; 5 series of consecutive cases collected in hospitals by gynecologists and pediatricians. Dr. Lenz continued to receive reports connecting the deformed babies with the prescription of the drug for the mothers at the rate of 3 to 10 per day.

Dr. A. L. Spiers, a Scottish physician, searched the prescription records of mothers of deformed babies to determine whether and when the expectant mothers had taken thalidomide. Reporting his findings in the Lancet of February 10, 1962, he stated:

"During the past year 10 babies with major limb defects were born in Stirlingshire maternity units. At least eight of the mothers had thalidomide prescribed for them in the early weeks of pregnancy. This confirms a similar association found in Europe and elsewhere."

The drug was withdrawn from the German market on November 27, 1961, and from the British market on December 2, 1961. It was not withdrawn from the Canadian market until March 2, 1962, and some druggists were still selling their shelf supplies in April. It was taken off the market in Belgium on June 14, 1962, after one distraught mother in Liege had been charged with infanticide for destroying her malformed baby.

Meanwhile, well before there was any basis for associating the drug with any particular side effects, the American licensee for the product, Wm. S. Merrell, filed its new drug application on September 12, 1960. It was to be sold in the United States under the trade name, Kevadon. Ironically, the proposed labeling stressed the value of the drug in combating nausea in pregnancy.

A few months later there appeared in the British Medical Journal of January 14, 1961, a communication from the clinical research department of the British licensee, Distillers Co., reporting instances of patients receiving thalidomide who had developed "symptoms and signs suggestive of peripheral neuritis" (i.e., inflammation of the nerves in the feet and hands). Noting this report and other reports of damage to adult nervous tissue, which is notably resistant to injury, the medical officer of the FDA handling the application, Dr. Frances Kelsey, suspected the likelihood of more serious damage to embryonic nervous tissue. Accordingly, she kept delaying approval of the application on the grounds that the application was incomplete and that new information was required.

This resistance was in the face of strong pressure by the company. The following synopsis, submitted by HEW, reveals more graphically than could any general description, the types of tactics employed to get a new drug application approved, and the difficulties under which the medical officers operate under conditions where approval is automatic within a given time period unless FDA acts to the contrary:

"The new drug application was received on September 12, 1960. FDA medical officers found it incomplete and inadequate to demonstrate safety on November 10, 1960.

"Between that date and February 23, the firm contacted FDA medical officers 11 times and submitted additional information intended to establish safety of the product.

"On February 23, 1961, FDA again found the application incomplete. By this time it had learned from the medical literature of reports of neuorological toxicity from the drug. FDA called this to the firm's attention.

"The firm made 11 more contacts with FDA medical officers between that time and May 11, 1961. On April 19, 1961, Mr. Murray of the firm advised Dr. Ralph Smith of FDA that he (Murray) thought some pressure should be asserted. Murray said he wanted a "yes or no" decision. On May 9, 1961, Mr. Murray called Dr. Ralph Smith and referred to a letter from Dr. Frances Kelsey, an FDA officer, as somewhat libelous.

"On May 11, 1961, Mr. Murray of the firm met with three of FDA's medical officers. They advised him that FDA needed evidence that the drug would be safe during pregnancy. FDA felt that the evidence in the petition before us was inadequate to support labeling which stressed the value of the drug in pregnancy.

"The firm made 14 contacts with FDA medical officers between this time and September 7, 1961, designed to expedite clearance of its new drug application.

"On September 7, 1961, Mr. Murray of the firm arranged a conference with FDA medical officers at which some clinicians who had investigated the drug for the firm reported their experience with it. FDA medical officers again pointed out the inadequate evidence on safety of the drug in pregnancy.

"The firm made 10 more contacts with FDA between this time and November 30, 1961, designed to get the drug cleared for marketing.

"November 30, 1961, Mr. Murray of the firm advised FDA that the drug had been withdrawn from the German market because of reports that it caused birth defects in infants whose mothers had been taking the drug.

"On March 8, 1962, the firm withdrew the new drug application.

"Between September 12, 1960, when the application was first submitted and November 30, 1961, when the firm advised of the birth abnormalities, William S. Merrell contacted FDA's Bureau of Medicine 50 times in an effort to get this drug on the American market and a number of the efforts to get the new drug application approved were very vigorous."

The fact that thalidomide was not approved for sale in the United States was due in part to the insight and courage of FDA's medical officer and in part to the coincidence that just about the time that the grounds on which the application could be held to be incomplete were being exhausted, the reports began to appear in the European medical journals associating the drug with the malformed births. Had these reports appeared only a few months later, there is a strong probability that the drug would have been released for sale in the United States in 1961.

It could then, of course, have been ordered off the market, but what of the damage that would have been done in the interim? It is this very practice under which the FDA approves the marketing of a drug, only to have to take it off the market later, that constitutes one of the most serious weaknesses of the present law—a weakness which will only be slightly relieved under the bill reported by the committee. The very fact that a drug is new usually means that there is little in the way of independent and objective clinical studies to guide the FDA physicians in their work. Because of this lack of information and also because of the pressures engendered by the automatic approval requirement, the FDA has released too many drugs for sale only to have to take them off the market later as new information concerning side effects develops. Under this procedure it is the American people who unknowingly serve as guinea pigs for experiments by the drug companies.

The seriousness of the problem is indicated by the table presented below which lists the new drugs whose new drug applications were suspended or withdrawn after mid-1958. Particularly to be noted are those drugs with side effects which can lead to death—blood dyscrasias, carcinogenic effects, liver damage, and hepatitis. The table should constitute conclusive evidence that the medical officers of the FDA, who are trying to protect the American people from drugs with dangerous side effects, should have an adequate time period in which to assure themselves that the drug is safe, and that applications should not become effective automatically during any time period. If a drug company feels that the delay in his application is arbitrary or capricious, it, of course, has recourse to the courts.

[p. 22047]

[From the office of Senator Estes Kefauver, Democrat, of Tennessee, Aug. 20, 1962]

SENATOR KEFAUVER HAILS JUDICIARY COMMITTEE ACTION IN ADOPTING STRENGTHENING AMENDMENTS TO DRUG BILL

Senator ESTES KEFAUVER today hailed the action by the Senate Judiciary Committee in adopting strengthening amendments to S. 1552, the drug industry bill, as "a great step forward." "The passage of this bill," he stated, "should go a long way toward assuring the American people that drugs are not only safe but will do what is claimed for them.

"By adopting most of the substance of the President's strong recommendations sent to Chairman EASTLAND on August 4," the Senator said, "the committee has reported out a bill which should not only result in better, safer and more effective drugs, but in addition should provide physicians with honest information concerning their properties and prevent the dissemination of false and misleading information to doctors."

The Senator pointed out that the bill will thus accomplish two of the three objectives which he had in mind in introducing the measure on April 12, 1961, following an extensive 2-year investigation of the industry. In addition to providing for safer drugs and better information to doctors, he had hoped to bring about price reductions. By making it easier and safer for physicians to prescribe by generic names, the present bill should result in lower prices for nonpatented drugs. "But", he pointed out, "there is nothing in the committee's bill to reduce the present high and excessive prices of patented drugs, which constitute about 60 percent of all prescription sales. I hope to achieve this objective by offering amendments on the floor of the Senate to require compulsory licensing of prescription drugs where the price to the druggist represents a markup of more than 500 percent of the factory cost (including research) and to require that patent and license agreements on drugs be filed with the Commissioner of Patents to be available to the antitrust agencies."

In addition, the Senator stated that he intended to introduce an amendment explicitly granting the FDA authority to require animal testing on drugs before they are given to humans, either in clinical testing or through sales on the market.

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"But on nine specific points," the Senator added, "S. 1552 as amended in general accordance with the President's recommendations is generally the same as the bill in its original form, as introduced on April 12, 1961. These nine points are: efficacy, advertising, new drug clearance procedure, determination of generic names, certification of antibiotics, package inserts, labeling requirements, factory inspection, and quality manufacturing controls. A listing comparing the original with the present version of S. 1552 on these points is attached.

PROVISIONS IN S. 1552 (AS SUPPLEMENTED BY THE COMMITTEE AMENDMENTS) SIMILAR IN SUBSTANCE TO S. 1552, AS INTRODUCED ON APRIL 12,1961.

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3. New drug clearance procedure

Although the Committee amendment does not go as far as S. 1552 in its original form, which would have eliminated the time limit altogether for approval of a new drug application, it does away with the automatic approval feature of the present law and greatly extends the time period from the present 60 to 180 days, plus 120 more if the applicant seeks a hearing.

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[p. 22050]

1.2i (4) (d) Oct. 4: House agrees to conference report, pp. 22323–22325.

Mr. ROBERTS.

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Mr. Speaker, there were a few items in the House bill which had no corresponding provision in the Senate bill and vice versa, such as the animal feed provision in the House bill, confidentiality of information in the House bill, effect of State laws in the House bill, or registration of producers of drugs in the Senate bill, publication by the Department of Health, Education, and Welfare of drug information in the Senate bill as well as information on patents in the Senate bill.

These items were worked out to the satisfaction of the conference committee.

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[p. 22323]

Mr. Speaker, I move the previous question.

The previous question was ordered.

The SPEAKER pro tempore (Mr. HARRIS). The question is on agreeing to the conference report.

The question was taken.

Mr. ROBERTS of Alabama. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER. Evidently a quorum is not present.

The Doorkeeper will close the doors, the Sergeant-at-Arms will notify absent Members, and the Clerk will call the roll.

The question was taken; and there were—yeas 347, nays 0, not voting 88, as follows:

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So the conference report was agreed to.

[p. 22325]

1.2j HEART DISEASE, CANCER, STROKE AND KIDNEY DISEASE AMENDMENTS OF 1970

October 30, 1970, P.L. 91–515, Title VI, Section 601(d) (1) 84 Stat. 1311

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(d) (1) Subsection (g) of section 408 of the Food, Drug, and Cosmetic Act[97] is amended by striking out "as compensation for their services a reasonable per diem, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence." after "shall receive" and by inserting in lieu thereof "compensation and travel expenses in accordance with subsection (b) (5) (D) of section 706."

[p. 1311]

1.2j (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 91–1297, 91st Cong., 2d Sess. (1970)

[No Relevant Discussion on Pertinent Section]

1.2j (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 91–1090, 91st Cong., 2d Sess. (1970)

[No Relevant Discussion on Pertinent Section]

1.2j (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 91-1590, 91st Cong., 2d Sess. (1970)

[No Relevant Discussion on Pertinent Section]

1.2j (4) CONGRESSIONAL RECORD, VOL. 116 (1970)

1.2j (4) (a) Aug. 12: Amended and passed House, p. 28532

[No Relevant Discussion on Pertinent Section]

1.2j (4) (b) Sept. 9: Amended and passed Senate, p. 31013

[No Relevant Discussion on Pertinent Section]

1.2j (4) (c) Oct. 13: House agrees to conference report, pp. 36589–36591

[No Relevant Discussion on Pertinent Section]

1.2j (4) (d) Oct. 14: Senate agrees to conference report, pp. 36888–36892

[No Relevant Discussion on Pertinent Section]

1.2k COMPREHENSIVE HEALTH MANPOWER TRAINING ACT OF 1971

November 18, 1971, P.L. 92-157 Title III, §303(a), 85 Stat. 464

To amend title VII of the Public Health Service Act to provide increased manpower for the health professions, and for other purposes.

AN ACT

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—AMENDMENTS TO TITLE VII OF THE PUBLIC HEALTH SERVICE ACT

SHORT TITLE; REFERENCES TO ACT

SEC. 101. (a) This title may be cited as the "Comprehensive Health Manpower Training Act of 1971".

(b) Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

[p. 1]

TITLE III—MISCELLANEOUS

* * * * *

TECHNICAL AMENDMENTS TO OTHER ACTS

SEC. 303. (a) The fourth sentence of section 408(g) of the Food, Drug, and Cosmetic Act is amended by striking out ", which the Secretary shall by rules and regulations prescribe,". [p. 35]

1.2k(1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 92-258, 92d Cong. 1st Sess. (1971)

[No Relevant Discussion on Pertinent Section]

1.2k(2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 92-251, 92d Cong., 1st Sess. (1971)

[No Relevant Discussion on Pertinent Section]

1.2k(3) COMMITTEE OF CONFERENCE

H.R. REP. No. 92-578, 92d Cong., 1st Sess. (1971)

[No Relevant Discussion on Pertinent Section]

1.2k(4) CONGRESSIONAL RECORD, VOL. 117 (1971):

1.2k(4)(a) July 1: Considered and passed House

[No Relevant Discussion on Pertinent Section]

1.2k(4)(b) July 14: Considered and passed Senate, amended

[No Relevant Discussion on Pertinent Section]

1.2k(4)(c) Oct. 19: Senate agreed to conference report

[No Relevant Discussion on Pertinent Section]

1.2k(4)(d) Nov. 9: House agreed to conference report

[No Relevant Discussion on Pertinent Section]

1.2l FEDERAL ENVIRONMENTAL PESTICIDE CONTROL ACT OF 1972

October 21, 1972, P.L. 92-516, § 3(3), 86 Stat. 998

AN ACT

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Environmental Pesticide Control Act of 1972". [p. 1]

AMENDMENTS TO OTHER ACTS

SEC. 3. The following Acts are amended by striking out the terms "economic poisons" and "an economic poison" wherever they appear and inserting in lieu thereof "pesticides" and "a pesticide" respectively:

* * * * *

(3) The Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

[p. 26]

1.21(1) HOUSE COMMITTEE ON AGRICULTURE

H.R. REP. No. 92-511, 92d Cong., 1st Sess. (1971)

[No Relevant Discussion on Pertinent Section]

1.21(2) SENATE COMMITTEE ON AGRICULTURE AND FORESTRY

S. REP. No. 92-838, 92d Cong., 2d Sess. (1972)

[No Relevant Discussion on Pertinent Section]

1.21(3) SENATE COMMITTEE ON COMMERCE

S. REP. No. 92-970, 92d Cong., 2d Sess. (1972)

[No Relevant Discussion on Pertinent Section]

1.21(4) COMMITTEE OF CONFERENCE

H.R. REP. No. 92-1540, 92d Cong., 2d Sess. (1972)

[No Relevant Discussion on Pertinent Section]

1.21(5) CONGRESSIONAL RECORD:

1.21(5)(a) VOL. 117 (1971), Nov. 8, 9: Considered and passed House;

[No Relevant Discussion on Pertinent Section]

1.21(5)(b) VOL. 118 (1972), Sept. 26: Considered and passed Senate, amend;

[No Relevant Discussion on Pertinent Section]

1.21(5)(c) VOL. 118 (1972), Oct. 5; Senate agreed to conference report;

[No Relevant Discussion on Pertinent Section]

1.21(5)(d) VOL. 118 (1972), Oct. 12: House agreed to conference report;

[No Relevant Discussion on Pertinent Section]

1.3 STUDIES OF EFFECTS IN USE OF CHEMICALS, AS AMENDED

16 U.S.C. §742d-1

§ 742d-1. Studies of effects in use of chemicals

The administrator of the Environmental Protection Agency is authorized and directed to undertake comprehensive continuing studies on the effects of insecticides, herbicides, fungicides, and pesticides, upon the fish and wildlife resources of the United States, for the purpose of determining the amounts, percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and the amounts, percentages, mixtures, or formulations that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting, or other treatment. (Pub. L. 85-582, § 1, Aug. 1, 1958, 72 Stat. 479; 1970 Reorg. Plan No. 3, § 2(a) (2) (i), eff. Dec. 2. 1970, 35 F.R. 15623 84 Stat.——.)

1.3a PESTICIDE RESEARCH ACT

August 1, 1958, P.L. 85-582, 72 Stat. 479

AN ACT

To authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following application of these materials and to provide basic data on the various chemical controls so that forests, croplands, wetlands, rangelands and other lands can be sprayed with minimum losses of fish and wildlife.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Secretary of the Interior is authorized and directed to undertake comprehensive continuing studies on the effects of insecticides, herbicides, fungicides and pesticides, upon the fish and wildlife resources of the United States, for the purpose of determining the amounts, percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and the amounts, percentages, mixtures, or formulations that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting or other treatment.

Sec. 2. The sum of $280,000 per annum is hereby authorized to be appropriated to carry out the objectives of this Act.

Approved August 1, 1958.

[p. 479]

1.3a (1) SENATE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

S. REP. No. 1592, 85th Cong., 2d Sess. (1958)

RESEARCH ON THE EFFECTS OF INSECTICIDES ON FISH AND WILDLIFE

MAY 19, 1958.—Ordered to be printed

Mr. MAGNUSON, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany S. 2447]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (S. 2447) to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, and fungicides upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following spraying, and to provide basic data on the various chemical controls so that forests, croplands, and marshes can be sprayed with minimum losses of fish and wildlife, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

PURPOSE OF THE BILL

S. 2447, as amended and approved by unanimous vote of your committee, would authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and pesticides upon fish and wild life for the purpose of preventing losses of those invaluable natural resources following application of these materials, and to provide basic data on various chemical controls. This research and study will, it is anticipated determine the amounts and percentages of such formulations and chemicals that may be used on wet lands, rangelands, and other lands with a minimum loss of fish and wildlife.

COMMITTEE ACTION

Public hearings were held by our committee on this legislation, and everyone desiring to testify was given an opportunity to be heard. Appearing and speaking in favor of this legislation were the following: Hon. Lee Metcalf, United States Representative [p. 1] from the First District of Montana; Lansing A. Parker, Assistant Director for Wildlife, Bureau of Sports Fisheries and Wildlife, Department of the Interior; James D. Dewitt, Chief Chemist, Bureau of Sports Fisheries and Wildlife, Department of the Interior; John H. Baker, president, National Audubon Society; Charles E. Jackson, general manager, National Fisheries Institute; E. S. Mosebrook, forester of the American Pulpwood Association; Charles H. Callison, conservation director, National Wildlife Federation; and Kenneth Pomeroy, representing the American Forestry Association. This bill is endorsed by farm groups, timber and logging industries, commercial fisheries, sportsmen, Federal and State officials.

NEED FOR THIS LEGISLATION

The current situation is, in a large part, due to the phenomenal growth in the use of new pesticidal compounds developed since World War II. The usefulness of these chemicals in combating ravages of insect pests is evidenced by reports that over 750 million pounds of pesticides having a value of over $256 million are produced in the United States each year. About two-thirds of this production is for domestic use on some 65 million acres of the Nation's land and water.

It is reported that there are over 6,000 aircraft, flying 541,000 hours, used to distribute or spray around 100 million gallons of liquid formulations, a major share of which are insecticidal.

The effects of these sprays, or dustings, has not only killed insects, but also destroyed wild and domestic animals and birds. A Florida operation to control sandflies resulted in the death of an estimated 1 million fish of 30 different species. A spray used to destroy tree-girdling mice has killed other mammals and birds. In March of 1958, approximately 3,000 geese died from eating treated grain used in Klamath Basin, Oreg., mouse-control campaign. Water runoff from some sprays on lands has killed fish. There is grave concern as to whether chemicals used to kill fire ants will even destroy earthworms, a major source of food for woodcock wintering in those areas. In Washington State, there has been damage to upland birds. In Montana, on the Yellowstone River, there was extensive damage to fish following application of DDT as part of the spruce budworm control program. A census of fish in seven Montana trout streams showed a loss of from 70 to 80 percent as a result of this spray.

This all points up to a pressing and urgent need for research studies to provide basic information which can be used as a guide to the future development and application of such formulations.

At the present time, the effects of many formulations are not fully known or understood.

Your committee believes this Congress should set in motion a research program in this all-important field.

This legislation carries no appropriation with it.

AGENCY COMMENTS

Department of the Interior

The Department of the Interior favors enactment of this legislation, with certain amendments. All amendments suggested by the Interior Department have been incorporated into the bill,and are shown below.

[p. 2]

Section 2 of the bill should be eliminated. This section would limit annual appropriations to the sum of $280,000.

The Department of Interior states:

> In our opinion, an adequate research program for the study of wildlife pesticide relationships probably would exceed this amount for certain years, and we believe that an arbitrary ceiling on appropriations for a program of this type would not be advisable.

In addition, the Department suggested the following perfecting amendments:

(1) Page 1, revise line 5 to read "of insecticides, herbicides, fungicides, and pesticides upon the fish and".

(2) Page 2, revise line 1 to read "determining the amounts, percentages, and formulations of such chemicals".

(3) Page 2, revise line 3 to read "amounts, percentages, mixtures, or formulations that can be used safely,".

(4) Page 2, revise line 5 to read "spraying, dusting, or other treatments."

(5) Amend the title of the bill to read:

> To authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following application of these materials, and to provide basic data on the various chemical controls so that forests, croplands, wet lands, rangelands, and other lands can be sprayed, dusted, or otherwise treated with minimum losses of fish and wildlife.

The report from the United States Department of the Interior on S. 2447 is appended hereto.

Comptroller General of the United States

The Comptroller General of the United States, in his letter dated July 19, 1957, stated:

> We have no information relative to the necessity for, or advisability of, the additional legislation proposed by S. 2447 and we, therefore, make no recommendation with respect to its enactment.

Department of Justice

The United States Department of Justice, in their letter dated July 10, 1957, stated:

> The bill has been examined, but, since the subject matter thereof is not related to any of the activities of the Department of Justice, we would prefer not to offer any comment concerning it.

Department of Health, Education, and Welfare

The Department of Health, Education, and Welfare did not reply to the committee's request for comments on this bill.

Agriculture Department

The Agriculture Department did not reply to the committee's request for comments on this legislation.

[p. 3]

DEPARTMENT OF THE INTERIOR,
OFFICE OF THE SECRETARY,
Washington, July 12, 1957.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Interstate and Foreign Commerce,
United States Senate, Washington, D. C.

DEAR SENATOR MAGNUSON: Your committee has requested a report on S. 2447, to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, and fungicides upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following spraying, and to provide basic data on the various chemical controls so that forests, croplands, and marshes can be sprayed with minimum losses of fish and wildlife.

We are agreeable to the enactment of this proposed legislation, although we believe the Fish and Wildlife Act of 1956 (70 Stat. 1119) and our general authority in this field provide sufficient authority to carry out the program contemplated by this bill. Enactment of specific legislation on this subject would, of course, express the interest of the Congress in this particular program that we consider to be vital to conservation of the Nation's fish and wildlife resources. Our budget estimates for fiscal year 1958 contain an item for pesticide studies on wildlife.

Sportsmen, conservationists, foresters, and farmers alike are concerned over the tremendous increases in pesticide applications to eliminate insects, weeds, diseases, and other pests. Each year more acreage is being treated with better and more efficient pesticides. Particularly impressive are the large numbers of extensive forest DDT spraying programs now being conducted yearly. Over 3.4 million acres of forests were sprayed last year, and more will be sprayed this year. Last year 65 million acres—more than one-sixth of the United States cropland—were treated with pesticides, the total amount of formulated pesticides being 3 billion pounds. The cost of applying these pesticides amounted to $256 million. Yet crop losses on untreated areas were estimated at $7.5 billion.

The importance of our forests and agricultural crops is unquestioned. Both are vitally needed. Likewise, insect and other pesticide-control operations are necessary. However, pesticide-control programs have gone ahead without adequate information on the effects which the pesticides have on fish and wildlife resources. A multi-billion-dollar recreation and commercial fishery industry of interest to more than 30 million Americans is involved.

The seriousness of the effects of insecticides on wildlife is emphasized by extensive spraying for the control of Dutch elm disease, which is now taking place. DDT is being used at as much as 10 times the concentration that can be tolerated by wildlife, and the resultant death of thousands of birds has aroused citizens in many parts of the country. Another current problem is the invasion of alfalfa fields by the yellow aphid. Required insecticidal treatments could have an appallingly serious effect on bird populations, as the yellow aphid has spread over millions of acres in the last 3 or 4 years.

In 1954, the CAA estimated that 31 million acres of land were sprayed by 6,000 airplanes during 541,000 hours of flying. In the Mirimichi River drainage of New Brunswick, Canada, following the airplane spraying of a DDT-oil

[p. 4]

solution to control a forest pest, the spruce budworm, serious losses of salmonid fish occurred. Heavy depletions in fish populations also occurred in the Yellowstone River drainage of Montana and Wyoming in 1955, following similar control operations for the spruce budworm. In the 100-mile section of the river affected, the value of the fishery has been estimated at $20,000 per mile annually, giving the fish an annual value (in terms of expenditures by fishermen) of $2 million. These instances of fish losses emphasize the need for more knowledge upon which to predict the effects of DDT applications. When a DDT spray operation is contemplated, the sponsors of the project should be able to obtain advice from Federal and State conservation officials on physiological problems, methods of application, formulations, and the timing of applications to minimize fish and wildlife losses.

In view of our responsibilities under treaty obligations with Canada and Mexico for the protection and management of migrating birds, including waterfowl, and for the protection and management of fish in Federal waters, funds are necessary to support research to determine the effects of insecticides on fish and wildlife. Sufficient basic research has not been accomplished to predict losses or to properly advise operating agencies on means of obtaining effective control and, at the same time, avoiding unnecessary fish and wildlife mortality.

Combined laboratory and field investigations in cooperation with other governmental agencies, such as the United States Forest Service, are necessary to obtain the needed facts. Among the pesticide-wildlife relationships that should be studied are the following:

(1) Tests of toxicity of new insecticides for birds, mammals, and fish.

(2) Development of diagnostic tests to permit determinations as to whether or not animals were killed by specific insecticides or other pesticides.

(3) Studies of application of insecticides in forest pest control, such as bark and spruce budworm.

(4) Studies of the effects on fish and wildlife of controlling the white-fringed beetle, Japanese beetle, grasshoppers, Mormon crickets, corn borer, and a host of other farm pests in all regions.

(5) Marsh studies on mosquito production and control in relationship to waterfowl habitat preservation. These studies would involve development of alternate methods of controlling mosquitoes, as well as testing new insecticides as to their effects on waterfowl and other desirable forms of marsh wildlife.

If favorable action is taken on this bill, we recommend that section 2 be eliminated therefrom. This section would limit annual appropriations for these purposes to the sum of $280,000. In our opinion, an adequate research program for the study of wildlife-pesticide relationships probably would exceed this amount for certain years, and we believe that an arbitrary ceiling on appropriations for a program of this type would not be advisable. In addition, we suggest the following perfecting amendments:

(1) Page 1, revise line 5 to read: "of insecticides, herbicides, fungicides, and pesticides upon the fish and".

(2) Page 2, revise line 1 to read: "determining the amounts, percentages, and formulations of such chemicals".

[p. 5]

(3) Page 2, revise line 3 to read: "amounts, percentages, mixtures, or formulations that can be used safely,".

(4) Page 2, revise line 5 to read: "spraying, dusting, or other treatments."

(5) Amend the title of bill to read: "To authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides upon fish and wildlife for the purpose of preventing losses of these invaluable natural resources following application of these materials, and to provide basic data on the various chemical controls so that forests, croplands, wet lands, rangelands, and other lands can be sprayed, dusted, or otherwise treated with minimum losses of fish and wildlife."

The Bureau of the Budget has advised us that there would be no objection to the submission of this report to your committee.

Sincerely yours,

HATFIELD CHILSON,
Under Secretary of the Interior.

[p. 6]

1.3a (2) HOUSE COMMITTEE ON MERCHANT MARINE AND FISHERIES

H.R. REP. No. 2181, 85th Cong., 2d Sess. (1958)

AUTHORIZING RESEARCH ON INSECTICIDES, HERBICIDES, FUNGICIDES, AND OTHER PESTICIDES BY THE SECRETARY OF THE INTERIOR

JULY 16, 1958.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. BONNER, from the Committee on Merchant Marine and Fisheries, submitted the following

REPORT

[To accompany S. 2447]

The Committee on Merchant Marine and Fisheries, to whom was referred the bill (S. 2447) to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following application of these materials and to provide basic data on the various chemical controls so that forests, croplands, wetlands, rangelands, and other lands can be sprayed with minimum losses of fish and wildlife, having considered the same, report favorably thereon with amendment and recommend that the bill as amended do pass.

The amendment is as follows:

On page 2, after line 8, add another section, reading as follows:

> Sec. 2. The sum of $280,000 per annum is hereby authorized to be appropriated to carry out the objectives of this Act.

PURPOSE OF THE BILL

The purpose of the bill S. 2447 is to express the intent of the Congress that the Secretary of the Interior increase his efforts to determine the effects upon fish and wildlife of the many lethal forms of insecticides, pesticides, and fungicides presently being developed in aid of agriculture. It is probable that there exists sufficient authority at present to conduct the necessary research but the fact remains that it is not being conducted.

[p. 1]

1.3a (3) CONGRESSIONAL RECORD, VOL. 104 (1958)

1.3a (3) (a) May 29: Passed Senate, pp. 9797–9798

STUDY OF THE EFFECTS OF INSECTICIDES, HERBICIDES, AND FUNGICIDES UPON FISH

Mr. MANSFIELD. Mr. President, I ask unanimous consent that the unfinished business be laid aside temporarily, so that the Senate may proceed to the consideration of the three matters to which I have referred. First, I ask that the Senate proceed to the consideration of Calendar No. 1622, S. 2447.

The PRESIDING OFFICER. The bill will be stated by title.

The CHIEF CLERK. A bill (S. 2447) to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, and fungicides upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following spraying and to provide basic data on the various chemical controls so that forests, croplands, and marshes can be sprayed with minimum losses of fish and wildlife.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Interstate and Foreign Commerce, with amendments on page 1, line 5, after the word "herbicides", to strike out "and fungicides" and insert "fungicides and pesticides"; on page 2, line 1, after the word "of", to strike out "determining the amounts and percentages of such chemicals that are lethal to or injurious to fish and wildlife and the amounts or percentages or mixtures which can be used safely, and thereby prevent losses of fish and wildlife from such spraying" and insert "determining the amounts, percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and the amounts, percentages, mixtures, or formulations that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting, or other treatment."

And, after line 10, to strike out:

SEC. 2. The sum of $280,000 per annum is hereby authorized to be appropriated to carry out the objectives of this act.

So as to make the bill read:

Be it enacted, etc., That the Secretary of the Interior is authorized and directed to undertake comprehensive continuing studies on the effects of insecticides, herbicides, fungicides and pesticides, upon the fish and wildlife resources of the United States, for the purpose of determining the amounts, percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and the amounts, percentages, mixtures, or formulation that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting, or other treatment.

The amendments were agreed to.

Mr. MAGNUSON. Mr. President, Senate bill 2447 was unanimously reported by the Committee on Interstate and Foreign Commerce.

I ask unanimous consent to have printed in the RECORD at this point extracts from the report on the bill.

There being no objection, the extracts from the report (No. 1592) were ordered to be printed in the RECORD, as follows:

PURPOSE OF THIS BILL

S. 2447, as amended and approved by unanimous vote of your committee, would authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and pesticides upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following application of these materials, and to provide basic data on various chemical controls. This research and study will, it is anticipated, determine the amounts and percentages of such formulations and chemicals that may be used on wet lands, rangelands, and other lands with a minimum loss to fish and wildlife.

COMMITTEE ACTION

Public hearings were held by our committee on this legislation, and everyone desiring to testify was given an opportunity to be heard. Appearing and speaking in favor of this legislation were the following: Hon. Lee Metcalf, United States Representative from the First District of Montana; Lansing A. Parker, Assistant Director for Wildlife, Bureau of Sports [p. 9797] Fisheries and Wildlife, Department of the Interior; James D. Dewitt, chief chemist, Bureau of Sports Fisheries and Wildlife, Department of the Interior; John H. Baker, president, National Audubon Society; Charles E. Jackson, general manager, National Fisheries Institute; H. S. Mosebrook, forester of the American Pulpwood Association; Charles H. Callison, conservation director, National Wildlife Federation; and Kenneth Pomeroy, representing the American Forestry Association. This bill is endorsed by farm groups, timber and logging industries, commercial fisheries, sportsmen, Federal and State officials.

NEED FOR THIS LEGISLATION

The current situation is, in a large part, due to the phenomenal growth in the use of new pesticidal compounds developed since World War II. The usefulness of these chemicals in combating ravages of insect pests is evidenced by reports that over 750 million pounds of pesticides having a value of over $256 million are produced in the United States each year. About two-thirds of this production is for domestic use on some 65 million acres of the Nation's land and water.

It is reported that there are over 6,000 aircraft, flying 541,000 hours, used to distribute or spray around 100 million gallons of liquid formulations, a major share of which are insecticidal.

The effects of these sprays, or dusting, has not only killed insects, but also destroyed wild and domestic animals and birds. A Florida operation to control sandflies resulted in the death of an estimated 1 million fish of 30 different species. A spray used to destroy tree-girdling mice has killed other mammals and birds. In March of 1958 approximately 3,000 geese died from eating treated grain used in Klamath Basin, Oreg., mouse-control campaign. Water runoff from some sprays on lands has killed fish. There is grave concern as to whether chemicals used to kill ants will even destroy earthworms, a major source of food for woodcock wintering in those areas. In Washington State, there has been damage to upland birds. In Montana, on the Yellowstone River, there was extensive damage to fish following application of DDT as part of the spruce budworm control program. A census of fish in 7 Montana trout streams showed a loss of from 70 to 80 percent as a result of this spray.

This all points up to a pressing and urgent need for research studies to provide basic information which can be used as a guide to the future development and application of such formulations.

At the present time, the effects of many formulations are not fully known or understood. Your committee believes this Congress should set in motion a research program in this all-important field.

This legislation carries no appropriation with it.

Mr. CURTIS. Mr. President, will the Senator from Washington yield?

Mr. MAGNUSON. I yield.

Mr. CURTIS. Does the bill provide for a new program, or the continuation of a program?

Mr. MAGNUSON. It is a combination of both. The Agriculture Department and the Department of the Interior have been somewhat concerned for many years in their research as to the effect of insecticides on crops and on fish and wildlife. The departments want authority to have a separate study made in this field.

Mr. CURTIS. Does the bill have the support of the full committee?

Mr. MAGNUSON. Yes. It was unanimously reported.

Mr. CURTIS. How about the Department?

Mr. MAGNUSON. It is a departmental bill. It was introduced at the request of the Department.

Mr. CURTIS. I thank the Senator.

The PRESIDING OFFICER. The bill is open to further amendment.

If there be no further amendment to be offered, the question is on the engrossment and third reading of the bill.

The bill (S. 2447) was ordered to be engrossed for a third reading, read the third time, and passed.

The title was amended, so as to read: "A bill to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following application of these materials and to provide basic data on the various chemical controls so that forests, croplands, wetlands, rangelands and other lands can be sprayed with minimum losses of fish and wildlife."

[p. 9798]

1.3a (3) (b) July 21: Amended and passed House, p. 14439

[No Relevant Discussion on Pertinent Section]

1.3a (3) (c) July 23: Senate concurs in House amendments, p. 14741

[No Relevant Discussion on Pertinent Section]

1.3b FISH AND WILDLIFE STUDIES

September 16, 1959, P.L. 86–279, 73 Stat. 563

AN ACT

To amend the Act of August 1, 1958, to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 2 of the Act of August 1, 1958, providing for continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources and for other purposes is amended to read as follows:

"Sec. 2. The sum of $2,565,000 per annum is hereby authorized to be appropriated to carry out the objectives of this Act."

Approved September 16, 1959. [p.563]

1.3b (1) SENATE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

S. REP. No. 708, 86th Cong., 1st Sess. (1959)

RESEARCH AND STUDIES ON INSECTICIDES

AUGUST 13 (legislative day, AUGUST 12), 1959.—Ordered to be printed

Mr. MAGNUSON, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany S. 1575]

The Committee on Interstate and Foreign Commerce, to which was referred the bill (S. 1575) to amend the act of August 1, 1958, to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

Public hearings were held by your committee on the amended bill, and everyone desiring to testify was given an opportunity to be heard.

PURPOSE OF THE BILL

S. 1575 directs the Secretary of the Interior to continue the studies inaugurated in 1958, under Public Law 582.

The phenomenal growth in production and use of chemical control agents is illustrated by the fact that in 1940 these products had a wholesale value of about $40 million. Today it is $290 million and is estimated to reach $1 billion by 1975. One-sixth of all the croplands and millions of acres of forests, rangelands, and marshlands are treated annually with these chemicals. Most of these areas are important wildlife and fish habitat.

Some of the chemicals persist in the soil for periods of 3 to 5 years and longer. Certain organisms, such as earthworms (angleworms), living in treated soils or waters, tend to concentrate the poison in their body tissue. Hence fishes, crabs, shrimp, and oysters are affected when they feed upon contaminated organisms.

Determination of the effects of pesticidal materials upon important forms of animal life is a complex and time-consuming study. Much greater effort is needed to—

[p. 1]

(1) determine the acute and chronic toxicities of some 200 basic pesticidal chemicals now on the market, plus many others in various stages of development;

(2) conduct chemical analysis of plant and animal tissue to determine the presence of pesticide residues, to develop diagnostic procedures for determining suspected poisoning of fishes, birds, and mammals and for measuring the degree and duration of toxic conditions in fish and wildlife habitats;

(3) carry out field appraisals of immediate and long range effects of large scale pest control upon fish and wildlife populations; and (4) facilitate the compilation and dissemination of findings from research studies so that chemists, entomologists, and others may apply such knowledge in the development of new pest control materials, formulations, and techniques of application to minimize hazards to desirable forms of life.

COST

The Secretary of the Interior, June 9, 1959, recommends the enactment of S. 1575 if amended to eliminate the present appropriation authorization ($280,000) contained in the 1958 act. They believe that no specific appropriation authorization should be prescribed. As this research program develops funds can be requested in accordance with established budgeting procedures. The present appropriation is inadequate.

Estimated annual cost of this act is $700,000.

REPORT

The report of the Department of the Interior dated June 9, 1959, is set forth below:

DEPARTMENT OF THE INTERIOR,
OFFICE OF THE SECRETARY,
Washington, D.C., June 9, 1959.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Interstate and Foreign Commerce,
U.S. Senate, Washington, D.C.

DEAR SENATOR MAGNUSON: Your committee has requested a report on S. 1575, a bill to amend the act of August 1, 1958, to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources, and for other purposes. This bill would amend the 1958 act for the purpose of authorizing increased appropriations to carry out the studies specified by that act. The act now authorizes the appropriation of $280,000 annually. By the terms of this bill, annual appropriations of $2,565,000 would be authorized.

We recommend the enactment of this proposal if amended to eliminate the present appropriation authorization contained in the 1958 act.

We believe that no specific appropriation authorization should be prescribed in the act. As this research program develops and expands on a logical scientific basis, funds can be requested, as required by circumstances, in accordance [p. 2] with established budgetary procedures. Consequently, we believe that an arbitrary appropriation limitation on an important research program may prove to be inaccurate and unrealistic if the basic objectives of the program are to be realized. In any event, it is clear from our initial studies that because of the magnitude of the problem to which this legislation is directed, and the scope of the research that will be required, the present appropriation authorization is inadequate.

As directed by the 1958 act, we have begun research concerning the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of these natural resources. As this program of study gets underway, it is becoming clear that to understand adequately and to reduce the detrimental effects of diverse and extensive pest control activities upon fish and wildlife resources will require a continuing research effort of much greater magnitude than is currently authorized. Manpower and facilities afforded by the present program permit only limited study of a very small percentage of the wide array of recently developed insecticides and herbicides in relation to a few forms of animal life. Numerous new pesticidal materials employed as fungicides, nematocides, miticides, and rodenticides also require evaluation.

Before 1940, relatively small amounts of such chemicals as nicotine, rotenone, pyrethrum, and the arsenicals were used for insect control. During and following World War II a rapid changeover to DDT, heptachlor, dieldrin, TEPP, malathion, and related compounds occurred. The phenomenal growth in production and use of chemical control agents is illustrated by the fact that in 1940 these products had a wholesale value of about $40 million, and in 1956 the total reached $290 million. By 1975 it is estimated that the wholesale value of such materials will reach $1 billion. Approximately one-sixth of all croplands and millions of acres of forests, rangelands, and marshlands are treated annually with these chemicals. Most of the treated areas constitute important habitat for numerous forms of fish and wildlife.

Studies to date have shown that DDT may kill fish and other aquatic life when applied at dosage rates in excess of one-quarter pound per acre; 2 pounds kills birds; and 5 pounds causes heavy mortality to mammals. Other insecticides such as heptachlor, dieldrin, aldrin, and endrin have acute toxicity ranges of from 15 to 200 times that of DDT. Some of these chemicals persist in the soil for periods of 3 to 5 years or longer. Certain food chain organisms, such as earthworms, living in treated soils or waters tend to concentrate the poisons in their body tissue. Hence, birds like the woodcock and robin as well as aquatic creatures—fishes, shrimp, crabs, and oysters—are affected when they feed upon contaminated organisms.

Pheasants, quail, and other species exposed to sublethal amounts of some pesticides in food materials suffer delayed chronic effects in the form of reduced reproductive capacity and survival of young. Persistent high levels of DDT have been found in the bodies of fishes months after temporary concentrations in the stream environment had dissipated. Bird numbers in several of the areas treated with heptachlor for imported fire ant control have been found to be reduced 75 to 85 percent. Populations of quail, wild turkey, and rabbits were also decimated or wiped out on some of the areas. In other parts of the country, particularly the Midwest, local populations of robins and other insectivorous songbirds have been depleted as a result of measures carried out for mosquito and Dutch elm disease control.

[p. 3]

Considerable aerial spraying is carried out over salt water marshes, particularly in the East, and control chemicals applied to land areas adjacent to inshore water reach important fish-producing water by drainage. There is thus need to determine the effects of pesticides on inshore aquatic life. Biologists, fishermen, and conservationists are concerned about the effects of these chemicals on fish, shrimp, and shellfish which live in inshore water as adults and on those species for which the marshes and estuaries are essential nursery grounds. Menhaden, shad, striped bass, croakers, and weakfish are reared in these areas during their early stages. Shrimp, crabs, oysters, and clams which support major commercial fisheries, spend a part or all of their lives in inshore environments.

Although the potential dangers from expanding use of insecticides is considered one of the most serious threats to valuable commercial fisheries today, no comprehensive program for related research has yet been activated. The limited work to date is incidental to other activities for which funds have been provided. Findings from studies carried out at the Galveston Laboratory show that lindane, an insecticide employed for the control of mosquitoes, is very toxic to shrimp. A total kill of laboratory test animals resulted within 24 hours after exposure to concentrations of the chemical as low as five parts per billion. Other findings reveal that crabs may be killed by eating fish flesh containing low levels of malathion.

Determination of the effects of pesticidal materials upon important forms of animal life is a complex and time-consuming study. Much greater effort is needed to: (1) Determine the acute and chronic toxicities of some 200 basic pesticidal chemicals now on the market, plus many others in various stages of development; (2) conduct chemical analysis of plant and animal tissue to determine the presence of pesticide residues, to develop diagnostic procedures for determining suspected poisoning of fishes, birds, and mammals and for measuring the degree and duration of toxic conditions in fish and wildlife habitats; (3) carry out field appraisals of immediate and long-range effects of large-scale pest control operations upon fish and wildlife populations; and (4) facilitate the compilation and dissemination of findings from research studies so that chemists, entomologists, and others may apply such knowledge in the development of new pest control materials, formulations, and techniques of application to minimize hazards to desirable forms of life.

As required by the act of July 25, 1956 (70 Stat. 652), the attached additional information has been prepared concerning the estimated additional man-years of civilian employment and expenditures for the first 5 years of the program to which this legislation relates.

We have been advised by the Bureau of the Budget that there is no objection to the submission of this report to your committee. Such advice, we are informed by that Bureau, should not be construed as reflecting any commitment as to the necessity for any appropriations beyond those contained in the 1960 budget for pesticide research.

Sincerely yours,

ROSS LEFFLER,
Assistant Secretary of the Interior.

[p. 4]

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic, existing law in which no change is proposed is shown in roman, matter which is omitted is shown in brackets).

PUBLIC LAW 85-582, 85TH CONGRESS (72 STAT. 479)

AN ACT To authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following application of these materials and to provide basic data on the various chemical controls so that forests, croplands, wetlands, rangelands and other lands can be sprayed with minimum losses of fish and wildlife.

That the Secretary of the Interior is authorized and directed to undertake comprehensive continuing studies on the effects of insecticides, herbicides, fungicides and pesticides, upon the fish and wildlife resources of the United States, for the purpose of determining the amounts, percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and the amounts, percentages, mixtures, or formulations that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting, or other treatment.

"Sec. 2 [The sum of $280,000 per annum is hereby authorized to be appropriated to carry out the objectives of this Act.] *There is hereby authorized to be appropriated such sums as are necessary to carry out the purposes of this Act.*"

[p. 5]

1.3b (2) HOUSE COMMITTEE ON MERCHANT MARINE AND FISHERIES

H.R. REP. No. 975, 86th Cong., 1st Sess. (1959)

AUTHORIZING AND DIRECTING THE SECRETARY OF THE INTERIOR TO UNDERTAKE CONTINUING STUDIES OF THE EFFECTS OF INSECTICIDES, HERBICIDES, FUNGICIDES, AND OTHER PESTICIDES UPON FISH AND WILDLIFE

AUGUST 24, 1959.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. BONNER, from the Committee on Merchant Marine and Fisheries, submitted the following

REPORT

[To accompany H.R. 5813]

The Committee on Merchant Marine and Fisheries, to whom was referred the bill (H.R. 5813) to amend the act of August 1, 1958, to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PURPOSE OF THE BILL

The purpose of the bill is to increase substantially the authorized appropriation contained in the bill reported by this committee and enacted into law during the 85th Congress (Public Law

85–582). That bill authorized the appropriation of $280,000 annually to study the effects of insecticides, herbicides, fungicides, and other pesticides on fish and wildlife. At the time of the enactment of that bill the committee was informed that the specified amount of $280,000 was sufficient to institute such a program but that as it developed there probably would be a need for additional funds. Since the enactment of that legislation it has come to the attention of the committee that adverse effects upon wildlife of the insecticide programs being carried on, particularly by the Department of Agriculture, have proven much greater than anticipated. Many wildlife species are in imminent danger of destruction while successful efforts have been made to reduce the amount of insecticides being used in such programs, such as that [p. 1] of the fire ant eradication, there is reason to believe that even so the wildlife in the affected areas continues to be in danger of eradication.

The committee notes that the authorization contained in the bill for the expenditure of $2,565,000 is relatively small in comparison with the insecticide programs presently in operation.

The Department of the Interior recommends the enactment of the bill but suggests the elimination of the appropriation authorization limitation. It believes that an arbitrary appropriation limitation on an important research program may prove to be inaccurate and unrealistic if the basic objectives of the program are to be realized. However, the committee is of the view that the ceiling contained in the bill is a desirable one and that if the expenditure of larger amounts becomes necessary as the program develops, it would be in order for the Fish and Wildlife Service to request additional authorization as needed.

The reports of the Department of the Interior and the Department of Agriculture follow:

DEPARTMENT OF THE INTERIOR,
OFFICE OF THE SECRETARY,
Washington, D.C., June 9, 1959.

HON. HERBERT C. BONNER,
Chairman, Committee on Merchant Marine and Fisheries,
House of Representatives, Washington, D.C.

DEAR MR. BONNER: Your committee has requested a report on H.R. 5813, a bill to amend the act of August 1, 1958, to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources, and for other purposes. This bill would amend the 1958 act for the purpose of authorizing increased appropriations to carry out the studies specified by that act. The act now authorizes the appropriation of $280,000 annually. By the terms of this bill, annual appropriations of $2,565,000 would be authorized.

We recommend the enactment of this proposal if amended to eliminate the present appropriation authorization contained in the 1958 act.

We believe that no specific appropriation authorization should be prescribed in the act. As this research program develops and expands on a logical scientific basis, funds can be requested, as required by circumstances, in accordance with established budgetary procedures. Consequently, we believe that an arbitrary appropriation limitation on an important research program may prove to be inaccurate and unrealistic if the basic objectives of the program are to be realized. In any event, it is clear from our initial studies that because of the magnitude of the problem to which this legislation is directed, and the scope of the research that will be required, the present appropriation authorization is inadequate.

As directed by the 1958 act, we have begun research concerning the effects of insecticides, herbicides, fungicides, and other pesticides upon fish and wildlife for the purpose of preventing losses of these natural resources. As this program of study gets underway. it is becoming clear that to understand adequately and to reduce the detrimental effects of diverse and extensive pest control activities upon fish and wildlife resources will require a continuing research effort of much greater magnitude than is currently authorized. Man- [p. 2] power and facilities afforded by the present program permit only limited study of a very small percentage of the wide array of recently developed insecticides and herbicides in relation to a few forms of animal life. Numerous new pesticidal materials employed as fungicides, nematocides, miticides, and rodenticides also require evaluation.

Before 1940, relatively small amounts of such chemicals as nicotine, rotenone, pyrethrum, and the arsenicals were used for insect control. During and following World War II a rapid changeover to DDT, heptachlor, dieldrin, TEPP, malathion, and related compounds occurred. The phenomenal growth in production and use of chemical control agents is illustrated by the fact that in 1940 these products had a wholesale value of about $40 million, and in 1956 the total reached $290 million. By 1975 it is estimated that the wholesale value of such materials will reach $1 billion. Approximately one-sixth of all croplands and millions of acres of forests, rangelands, and marshlands are treated annually with these chemicals. Most of the treated areas constitute important habitat for numerous forms of fish and wildlife.

Studies to date have shown that DDT may kill fish and othe aquatic life when applied at dosage rates in excess of one-quarter pound per acre; 2 pounds kills birds; and 5 pounds causes heavy mortality to mammals. Other insecticides such as heptachlor, dieldrin, aldrin, and endrin have acute toxicity ranges of from 15 to 200 times that of DDT. Some of these chemical persist in the soil for periods of 3 to 5 years of longer. Certain food chain organisms, such as earthworms, living in treated soils or waters tend to concentrate the poisons in their body tissue. Hence, birds like the woodcock and robin as well as aquatic creates—fishes, shrimp, crabs, and oysters—are affected when they feed upon contaminated organisms.

Pheasants, quail, and other species exposed to sublethal amounts of some pesticides in food materials suffer delayed chronic effects in the form of reduced reproductive capacity and survival of young. Persistent high levels of

DDT have been found in the bodies of fishes months after temporary concentrations in the stream environment had dissipated. Bird numbers in several of the areas treated with heptachlor for imported fire ant control have been found to be reduced 75 to 85 percent. Populations of quail, wild turkey, and rabbits were also decimated or wiped out on some of the areas. In other parts of the country, particularly the Midwest, local populations of robins and other insectivorous songbirds have been depleted as a result of measures carried out for mosquito and Dutch elm disease control.

Considerable aerial spraying is carried out over salt water marshes, particularly in the East, and control chemicals applied to land areas adjacent to inshore water reach important fish-producing water by drainage. There is thus need to determine the effects of pesticides on inshore aquatic life. Biologists, fishermen, and conservationists are concerned about the effects of these chemicals on fish, shrimp, and shellfish which live in inshore water as adults and on those species for which the marshes and estuaries are essential nursery grounds. Menhaden, shad, striped bass, croakers, and weakfish are reared in these areas during their early stages. Shrimp, crabs, oysters, and clams, which support major commercial fisheries, spend a part or all of their lives in inshore environments.

[p. 3]

Although the potential dangers from expanding use of insecticides is considered one of the most serious threats to valuable commercial fisheries today, no comprehensive program for related research has yet been activated. The limited work to date is incidental to other activities for which funds have been provided. Findings from studies carried out at the Galveston Laboratory show that lindane, an insecticide employed for the control of mosquitoes, is very toxic to shrimp. A total kill of laboratory test animals resulted within 24 hours after exposure to concentrations of the chemical as low as five parts per billion. Other findings reveal that crabs may be killed by eating fish flesh containing low levels of malathion.

Determination of the effects of pesticidal materials upon important forms of animal life is a complex and time-consuming study. Much greater effort is needed to (1) determine the acute and chronic toxicities of some 200 basic pesticidal chemicals now on the market, plus many others in various stages of development; (2) conduct chemical analysis of plant and animal tissue to determine the presence of pesticide residues, to develop diagnostic procedures for determining suspected poisoning of fishes, birds, and mammals and for measuring the degree and duration of toxic conditions in fish and wildlife habitats; (3) carry out field appraisals of immediate and long-range effects of large-scale pest control operations upon fish and wildlife populations; and (4) facilitate the compilation and dissemination of findings from research studies so that chemists, entomologists, and others may apply such knowledge in the development of new pest control materials, formulations, and techniques of application to minimize hazards to desirable forms of life.

As required by the act of July 25, 1956 (70 Stat. 652), the attached additional information has been prepared concerning the estimated additional man-years of civilian employment and expenditures for the first 5 years of the program to which this legislation relates.

We have been advised by the Bureau of the Budget that there is no objection to the submission of this report to your committee. Such advice, we are informed by that Bureau, should not be construed as reflecting any commitment as to the necessity for any appropriations beyond those contained in the 1960 budget for pesticide research.

Sincerely yours,

(Signed) ROSS LEFFLER,
Assistant Secretary of the Interior.

[p. 4]

Estimated additional man-years of civilian employment and expenditures for 5-year program (preliminary)

	19CY[1]	19CY+1	19CY+2	19CY+3	19CY+4
Executive direction:					
Executive	0	2	2	2	
Clerical	0	1	2	2	
Stenographic	0	2	2	2	2
Total executive	0	5	6	6	6
Administrative service and support	0	0	0	0	0
Program:					
Laboratory and field	2	21	36	50	64
Supporting	2	13	27	44	61
Total program	4	34	63	94	125
Total estimated additional man-years	4	39	69	100	131
Estimated additional expenditures:					
Personal services	$180,000	$505,000	$780,000	$1,055,000	$1,330,000
Expenses[2]	100,000	275,000	500,000	725,000	950,000
Total estimated additional expenditures	280,000	780,000	1,280,000	1,780,000	2,280,000
Total costs:					
1st year					$280,000
2d to 5th years					6,120,000
5 years					6,400,000

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[1] CY—current year (fiscal year 1960).

[2] Includes $50,000 for contract services beginning CY+2.

DEPARTMENT OF AGRICULTURE,
Washington, D.C., June 4, 1959.

Hon. HERBERT C. BONNER,
Chairman, Committee on Merchant Marine and Fisheries,
House of Representatives.

DEAR CONGRESSMAN BONNER: This is in reply to your request of March 25, 1959, for a report on H.R. 5813, a bill to amend the act of August 1, 1958, to authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources, and for other purposes.

Since the bill covers work that would be performed by the Department of the Interior, we have no recommendation to make regarding its enactment.

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

TRUE D. MORSE, *Acting Secretary.*

CHANGES IN EXISTING LAW

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as introduced, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Law 85–582
85th Congress, S. 2447
August 1, 1958

AN ACT To authorize and direct the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources following application of these materials and to provide basic data on the various chemical controls so that forests, croplands, wetlands, rangelands and other lands can be sprayed with minimum losses of fish and wildlife.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Secretary of the Interior is authorized and directed to undertake comprehensive continuing studies on the effects of insecticides, herbicides, fungicides and pesticides, upon the fish and wildlife resources of the United States, for the purpose of determining the amounts percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and the amounts, percentages, mixtures, or formulations that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting, or other treatment.

[SEC. 2. The sum of $280,000 per annum is hereby authorized to be appropriated to carry out the objectives of this Act.]

Sec. 2. The sum of $2,565,000 per annum is hereby authorized to be appropriated to carry out the objectives of this Act.

[p. 6]

1.3b (3) CONGRESSIONAL RECORD, VOL. 105 (1959)

1.3b (3) (a) Aug. 19: Amended and passed Senate, p. 16345

[No Relevant Discussion on Pertinent Section]

1.3b (3) (b) Sept. 2: Amended and passed House, pp. 17768–17769

[No Relevant Discussion on Pertinent Section]

1.3b (3) (c) Sept. 10: Senate concurs in House amendments, p. 18938

STUDIES OF THE EFFECTS OF CERTAIN INSECTICIDES UPON FISH AND WILDLIFE

* * * * *

Mr. MAGNUSON. Mr. President, the bill authorized the appropriation of such sums as might be necessary to carry out the purposes of the act, which authorized and directed the Secretary of the Interior to undertake continuing studies of the effects of insecticides, herbicides, fungicides, and other pesticides, upon fish and wildlife for the purpose of preventing losses of those invaluable natural resources. The House amended the bill by placing a limit on the authorization.

Mr. President, I move that the Senate concur in the House amendment.

The PRESIDING OFFICER. The question is on agreeing to the motion of the Senator from Washington.

The motion was agreed to.

[p. 18938]

1.3c PROTECTION OF FISH AND WILDLIFE FROM PESTICIDES

October 1, 1965, P.L. 89–232, 79 Stat. 902

AN ACT

To amend the Act of August 1, 1958, relating to a continuing study by the Secretary of the Interior of the effects of insecticides, herbicides, fungicides, and other pesticides upon fish and wildlife for the purpose of preventing losses to this resource.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 2 of the Act of August 1, 1958 (72 Stat. 479), as amended by the Act of September 16, 1959 (73 Stat. 563), is amended to read as follows:

"SEC. 2. In order to carry out the provisions of this Act, there are authorized to be appropriated for the fiscal year ending June 30, 1966, not to exceed $3,200,000, and not to exceed $5,000,000 for each of the two fiscal years immediately following such year."

Approved October 1, 1965.

[p. 902]

1.3c (1) SENATE COMMITTEE ON COMMERCE

S. REP. No. 169, 89th Cong., 1st Sess. (1965)

PROTECTION OF FISH AND WILDLIFE FROM PESTICIDES

APRIL 28, 1965.—Ordered to be printed

Mr. MAGNUSON, from the Committee on Commerce, submitted the following

REPORT

[To accompany S. 1623]

The Committee on Commerce, to whom was referred the bill (S. 1623) to amend the act of August 1, 1958, relating to a continuing study by the Secretary of the Interior of the effects of insecticides, herbicides, fungicides, and other pesticides upon fish and wildlife for the purpose of preventing losses to this resource, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

PURPOSE OF THE BILL

The purpose of the bill, as amended, is to increase the authorized annual appropriation for pesticide research by the Department of the Interior from $2,565,000 to $3.2 million for fiscal year 1966 and $5 million annually for fiscal years 1967 and 1968.

BACKGROUND

On May 15, 1963, the President's Science Advisory Committee issued its report on the "Use of Pesticides." The Committee cited the compelling need for participation by the Interior Department in the establishment of a "continuing network to monitor residue levels in air, water, soil, man, wildlife, and fish." This Committee similarly urged "expanded research and evaluation by the Department of the Interior of the toxic effects of pesticides on wild vertebrates and invertebrates."

"The study of wildlife," the President's Committee concluded, "presents a unique opportunity to discover the effects on the food chain of which each animal is a part, and to determine possible pathways through which accumulated and, in some cases, magnified [p. 1] pesticide residues can find their way directly or indirectly to wildlife and to man."

During the last Congress, the Commerce Committee held hearings on legislation to eliminate the present $2,565,000 authorization ceiling on pesticide research by the Department of the Interior.

Among the witnesses who appeared before the committee was Rachel Carson, the famed biologist, whose "Silent Spring" alerted millions of Americans to the potential danger from the uncontrolled use of pesticides.

The committee reported and the Senate passed, unanimously S. 1251, which would have authorized the appropriation of $3.2 million for fiscal year 1965 and $5 million annually thereafter. Senate action came too late in the session to enable the measure to go to conference with the House for the resolution of differing provisions between the Senate and House versions.

In his message to Congress on natural beauty early this year, President Johnson dealt with the limitation on pesticide research:

> Pesticides may effect living organisms wherever they occur.
>
> In order that we may better understand the effects of those compounds, I have included increased funds in the budget for use by the Secretaries of Agriculture, Interior, and Health, Education, and Welfare to increase their research efforts on pesticides through the environment; study the means by which pesticides break down and disappear in nature; and to keep a constant check on the level of pesticides in our water, air, soil, and food supply.
>
> I have asked the Secretary of the Interior to submit legislation to eliminate the ceiling on pesticide research.

COMMITTEE CONSIDERATION OF THE BILL

S. 1623, to eliminate the ceiling, was introduced by the chairman and Mrs. Neuberger at the request of the Secretary of the Interior. The committee was of the opinion that a ceiling should be placed on the authorized appropriations for pesticide research in line with the current needs for such research and that Congress should have an opportunity to review these needs again in 3 years. The committee was informed by the Department of the Interior that a ceiling of $3.2 million for fiscal year 1966 and $5 million annually thereafter would be adequate to support the necessary forseeable expansion in the Department. Therefore, the committee recommends the adoption of an amendment increasing the authorization for pesticide research for $3.2 million for fiscal 1966 and $5 million annually for fiscal years 1967 and 1968.

[p. 2]

1.3c (2) HOUSE COMMITTEE ON MERCHANT MARINE AND FISHERIES

H.R. REP. No. 1002, 89th Cong., 1st Sess. (1965)

PROTECTION OF FISH AND WILDLIFE FROM PESTICIDES

SEPTEMBER 14, 1965.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. GARMATZ, from the Committee on Merchant Marine and Fisheries, submitted the following

REPORT

[To accompany S. 1623]

The Committee on Merchant Marine and Fisheries, to whom was referred the bill (S. 1623) to amend the act of August 1, 1958, relating to a continuing study by the Secretary of the Interior of the effects of insecticides, herbicides, fungicides, and other pesticides upon fish and wildlife for the purpose of preventing losses to this resource, having considered the same report favorably thereon without amendment, and recommend that the bill do pass.

PURPOSE OF THE BILL

The purpose of the bill is to increase the ceiling on authorized annual appropriations for pesticide research from $2,565,000 to $3.2 million for fiscal year 1966 and to $5 million annually for fiscal years 1967 and 1968.

[p. 1]

NEED FOR THE LEGISLATION

Your committee feels that an excellent explanation for the need of this legislation can be found in the statement of Dr. Stanley A. Cain, Assistant Secretary of the Interior for Fish and Wildlife, presented at the open hearings on June 22, 1965, before the Subcommittee on Fisheries and Wildlife Conservation, on S. 1623 and related bills. Excerpts from that statement are as follows:

> The Fish and Wildlife Service has studied the effects of chemical pesticides, particularly DDT, on fish and wildlife for more than 20 years. After receiving specific authorization and appropriations, the Service has broadened its studies to cover other chemicals and other species of animals.
>
> Interior is a user of pesticides in many of its programs, and is not opposed to their use, because we know the benefits that these chemicals can bring. At the same time, through our background of studies of * * *, we know that some pesticides pose

serious hazards and must be used with extreme caution against proper targets.

Research to date has demonstrated some really disturbing facts about minute quantities of pesticide chemicals used in improper manner and reaching unexpected environments.

* * * * * * *

DDT concentrations of one part per billion will kill blue crabs in coastal estuaries within 8 days. Commercially im- [p. 2] portant brown and pink shrimp exposed to less than 0.5 part per billion of another chemical were paralyzed in 48 hours, and presumably would have died had they been in their natural environments.

Oysters exposed to DDT at 0.5 part per million in small tanks removed over half of the pesticides from the water within 6 hours and concentrated it in their bodies * * *.

The Department of the Interior is deeply concerned about the ways in which pesticides turn up in unlikely places. We have found them in penguins and seals in Antarctica as well as in animals in the far north, far removed from any local spray programs.

They are found in the wild game taken by sportsmen. Commercial fishermen have no control over the ways in which pesticides may reach and be stored in the flesh of their product. Although our past research has given us much information, we believe that much more should be obtained to prevent the decimation of fish and wildlife populations and the contamination of their environments.

For example, we hope to monitor the occurrence of pesticide residues in commercial fish and shellfish in their natural environments, in recreationally important fish species, and in wild birds and mammals * * *.

Much of the Department of the Interior's pesticide research programs must be extended to studying the long-term effects on fish and wildlife populations * * *.

Residues accumulated in fish and wildlife as they consume other animals are greatly magnified to the point where acute poisoning and tissue damage ultimately result. We know almost nothing about the biological and toxicological significance of continued exposure to small quantities of these chemicals either in animals or in man.

Neither do we know what happens when these chemicals are mixed in small quantities over long periods of time * * *.

> We like to believe that the Department of the Interior is on the right track in its current research on the ecological implications of pesticides to animals, particularly fish and game, and indirectly to man himself.
>
> * * * For these reasons, we feel that the current ceilings are too low. We also repeat the suggestion that no ceiling be imposed, relying instead upon the annual review of congressional appropriations committees to evaluate our progress and our use of these very important funds for pesticide research.

Your committee noted that on May 15, 1963, the President's Science Advisory Committee issued its report on the "Use of Pesticides," wherein it recommended—

> expanded research and evaluation by the Department of the Interior of the toxic effects of pesticides on wild vertebrates and invertebrates.

Your committee further noted that the witnesses from the Departments of Interior and Agriculture, in their support of the legislation, stated that the President in his message to the Congress [p. 3] on natural beauty, of February 8, 1965, pointed to the need for increased research on pesticides and recommended the removal of the ceiling on such research. Further, the witnesses stated that consistent with the President's request, legislation was introduced in the Senate which would eliminate the ceiling on pesticide research and authorize such sums as may be necessary to carry out the purposes of the act (S. 1623 as originally introduced).

Your committee was advised by the witness from the Interior Department that the maximum amount authorized to be appropriated under the act of August 1, 1958, $2,565,000, had been appropriated for fiscal year 1965, and that the Department of the Interior's planned program for that year called for expenditures of about $3.5 million. It was further explained that because of the increased need for expanded pesticide research, projected plans call for the expenditure of approximately $5 million for the next fiscal year and $7 million each year thereafter. In view of the foregoing, your committee is of the opinion that a ceiling should be placed on the authorized appropriation approximating the current needs. Therefore, your committee unanimously recommends the adoption of S. 1623, which would increase the authorization for pesticide research to $3.2 million for fiscal 1966, and $5 million annually for fiscal years 1967 and 1968.

It was the thinking of your committee that this legislation should be limited to a period of 3 years so that at the termination of the program the Congress would have an opportunity again to review the needs for pesticide research.

COST OF THE LEGISLATION

The cost of this legislation authorized by S. 1623 for fiscal year 1966 is $3.2 million and $5 million annually for fiscal years 1967 and 1968.

DEPARTMENTAL REPORTS

Departmental reports received on the bill are as follows:

* * * * * * *

[p. 4]

1.3c (3) CONGRESSIONAL RECORD, VOL. III (1965)

1.3c (3) (a) April 29: Amended and passed Senate, pp. 8967–8968

[No Relevant Discussion on Pertinent Section]

1.3c (3) (b) Sept. 20: Passed House, p. 24374

PROTECTION OF FISH AND WILDLIFE FROM PESTICIDES

Mr. DINGELL. Mr. Speaker, I move to suspend the rules and pass the bill (S. 1623) to amend the act of August 1, 1958, relating to a continuing study by the Secretary of the Interior of the effects of insecticides, herbicides, fungicides, and other pesticides upon fish and wildlife for the purpose of preventing losses to this resource.

The Clerk read as follows:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled. That section 2 of the Act of August 1, 1958 (72 Stat. 479), as amended by the Act of September 16, 1959 (73 Stat. 563), is amended to read as follows:

"SEC. 2. In order to carry out the provisions of this Act, there are authorized to be appropriated for the fiscal year ending June 30, 1966, not to exceed $3,200,000, and not to exceed $5,000,000 for each of the two fiscal years immediately following such year."

The SPEAKER. Is a second demanded?

Mr. PELLY. Mr. Speaker, I demand a second.

The SPEAKER. Without objection, a second will be considered as ordered.

There was no objection.

Mr. DINGELL. Mr. Speaker, this is an important piece of legislation. It has been endorsed unanimously by every Federal agency that has reported upon it. It has the support of all the private conservation agencies and the State game and fish conservation commissions across the country.

This piece of legislation imposes a 3-year limitation on what otherwise was a program that was open-ended insofar as time is concerned. It raises the existing amount of money authorized for research into the effects of pesticides on fish and wildlife from $2,565,000 to $3,200,000 for the first year, and then to $5 million for each of the next 2 years.

It is a piece of legislation which has an important place in conservation and is one of the pieces of legislation which President Johnson mentioned in one of his messages to the Congress.

Mr. PELLY. Mr. Speaker, I yield myself 1 minute.

Mr. Speaker, S. 1623 would increase the ceiling on authorized annual appropriations for pesticide research from $2,565,000 to $3,200,000 annually for fiscal years 1967 and 1968.

I think the hearings adequately justified the need for this increase. Already, research has indicated some frightening facts as to the danger to wildlife by minute quantities of chemicals which find their way into and pollute our streams and other waters.

I support this legislation which was approved unanimously by the House Subcommittee on Fish and Wildlife.

I urge its adoption.

Mr. SCHMIDHAUSER. Mr. Speaker, I rise in support of S. 1623, a bill designed to afford greater protection for fish and wildlife from pesticides. There is no program more closely related to the long-range conservation objectives of our Nation than this measure. All of the great programs which have been enacted in Congress during this session, and this most assuredly has been a "conservation" Congress, would have little effect if our Nation's fish and wildlife were silently destroyed because we do not fully understand the lethal effects of chemicals which are designed to control pests. This is why it is especially important that the authority of the Secretary of Interior to authorize scientific study of the effects of pesticides and other poisonous chemicals upon our Nation's fish and wildlife be continued and expanded.

I therefore urge passage of this much-needed legislation.

The SPEAKER. The question is, Will the House suspend the rules and pass the bill, S. 1623?

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

1.3d PESTICIDE RESEARCH

July 11, 1968, P.L. 90–394, 83 Stat. 338

AN ACT

To amend section 2 of the Act of August 1, 1958, as amended, in order to prevent or minimize injury to fish and wildlife from the use of insecticides, herbicides, fungicides, and other pesticides.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 2 of the Act of August 1, 1958 (72 Stat. 479), as amended (16 U.S.C. 742d–1 note), is amended to read as follows:

"SEC. 2. In order to carry out the provisions of this Act, there is authorized to be appropriated the sum of $3,500,000 for the fiscal year ending June 30, 1969, and for each of the two fiscal years immediately following such year. Such sums shall remain available until expended."

Approved July 11, 1968.

[p. 338]

1.3d (1) HOUSE COMMITTEE ON MERCHANT MARINE AND FISHERIES

H.R. REP. No. 1223, 90th Cong., 2d Sess. (1968)

PESTICIDE RESEARCH

MARCH 29, 1968.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. GARMATZ, from the Committee on Merchant Marine and Fisheries submitted the following

REPORT

[To accompany H.R. 15979]

The Committee on Merchant Marine and Fisheries to whom was referred the bill (H.R. 15979), to amend the act of August 1, 1958, in order to prevent or minimize injury to fish and wildlife from the use of insecticides, herbicides, fungicides, and pesticides, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill do pass.

The amendments are as follows:

On page 3, line 7, strike out "June 30, 1968,", and insert in lieu thereof the following: "June 30, 1969,".

On page 3, line 8, strike out "succeeding fiscal year.' ", and insert in lieu thereof the following: "of the two fiscal years immediately following such year.' ".

PURPOSE OF THE BILL

The purpose of the bill is to prevent or minimize injury to fish and wildlife from the use of insecticides, fungicides, pesticides, and other poisonous chemicals.

LEGISLATIVE BACKGROUND

The bill was introduced March 14, 1968, by Congressman Joseph E. Karth. It is identical to a bill previously introduced on January 10, 1967, by Congressman John D. Dingell.

The Subcommittee on Fisheries and Wildlife Conservation held hearings on the legislation on March 14, 1968.

The Department of Agriculture, in its report on the legislation, indicated that it had no objection to the bill to the extent it would

[p. 1]

provide new and more extensive research data on the relation of pesticides to fish and wildlife. However, it deferred to the Department of the Interior as to the need for this provision. The Department of Agriculture opposed the labeling provision in the bill—

section 1(b)—on the grounds that it would create a conflict of authority between the Secretaries of the Interior and Agriculture in the administration of the Federal Insecticide, Fungicide, and Rodenticide Act. Also, the objective of this provision is the subject of a 1964 interdepartmental agreement and is being carried out administratively among the Departments of the Interior, Agriculture, and Health, Education, and Welfare.

The Department of Health, Education, and Welfare reported that—

> We are in accord with the objectives of this bill. * * * We believe, however, that section 1 of the bill in regard to labeling is unnecessary * * * This interdepartmental agreement is intended to provide a mechanism for the efficient coordination of matters relating to pesticides which section 1 of H.R. 487 undertakes to remedy * * *
>
> We defer to the views of the Department of the Interior with respect to section 2 of the bill.

The Department of the Interior strongly recommended enactment of the legislation with certain amendments. It recommended that subsection (b) of section 1 be deleted as the objective of this subsection is the subject of the 1964 administrative agreement. It recommended that section 2 of the bill be deleted as the Department has ample authority under the Fish and Wildlife Act of 1956 and the Federal Water Pollution Control Act to carry out all that would be authorized by this section.

The Department did not deem legislation necessary in any way except to extend the research program beyond June 30, 1968. Accordingly, the Department suggested a draft bill which would extend the 1958 act authorization indefinitely. In addition, it would remove the dollar ceiling, as recommended by the President in the 89th Congress.

Although all agencies reporting on the legislation expressed opposition to the labeling provision of the bill, none expressed opposition to the objectives of the legislation, and all witnesses testifying at the hearings were in support of extending the pesticide research program. After giving careful consideration to all the evidence presented at the hearings and the departmental reports, your committee reported the bill as introduced except for the section pertaining to the authorization of funds. Your committee amended this section to limit the program to a period of 3 years only.

BACKGROUND AND NEED FOR THE LEGISLATION

Your committee feels that an excellent explanation for the need of this legislation can be found in a 1966 publication issued by the Fish and Wildlife Service, U.S. Department of the Interior, entitled "Fish, Wildlife, and * * * Pesticides." Excerpts from that publication are as follows:

Today, in the United States, 8,000 manufacturing firms mix about 500 chemical compounds into more than 60,000 formulations registered for use as pesticides. In 1964, the U.S. chemi- [p. 2] cal industry produced 783 million pounds of pesticides, of which three-quarters were for domestic use. Insecticides, rodenticides, and fumigants accounted for 444 million pounds; herbicides, 226 million; fungicides, 113 million.

It has been reported that about 1 acre in 10 in the continental United States is treated annually with an average of nearly 4 pounds of pesticides. The farmer uses most of the pesticides. Fifteen percent of the 460 million acres of farmland in the United States—69 million acres—produces crops requiring insecticides—corn, rice, cotton, vegetables, fruits, and nuts.

The Federal Government uses less than 5 percent of all pesticides used in the United States. About 15 percent of the total domestic figure is bought for home and garden use.

Some pesticides have hitchhiked great distances and persisted for long periods of time. Air currents, water runoff, dust particles, and living organisms have been their vehicles. * * * Residues have even been found in penguins and crabeater seals in Antarctica. DDT was found in the oil of fish that live far from land and in those caught off the coasts of four continents—ranging in concentrations from less than 1 part of DDT in 1 million parts of oil (1 part per million) to more than 300 parts per million. Often, fish do not die immediately or at the site of the pesticide exposure. In one recorded case, fish started dying 3 months after DDT was applied, and death reached downstream nearly 100 miles from the treatment site.

From 1960 to 1963, of 56 bald eagles found dead or incapacitated in 20 States and two Canadian Provinces, all but one (from Alaska) contained DDT.

The U.S. Public Health Service has reported traces of one or more chlorinated hydrocarbons in every major river system in the Nation. * * *

Pesticides are particularly significant to the fishing industry. Some of the most valuable species of fish and shellfish are also the most sensitive to pesticides. Ten marine animal groups make up 80 percent of the $381.2 million U.S. fishery.

Of the 10, five spend important parts of their lives in estuarine waters (where salt and fresh water meet) and are vulnerable to pesticides. The five are shrimp, mollusks, Pacific salmon, crabs, and menhaden (a member of the herring family used to make poultry feeds and oil).

During the past 4 years, the researchers have developed objective methods for measuring effects of pesticides. New chemicals sent by manufacturers are tested on plankton, shrimp, crabs, oysters, and one or two species of commercial fish. The researchers seek to assist in finding narrow-spectrum pesticides that may be used to control target pests without harm to other life.

Some pesticides paralyze shrimp or other crustaceans rather than kill them. The criteria for testing toxicity of this group are set by learning the concentrations of pesticide that will cause paralysis or death to half of the sample within 24 [p. 3] to 48 hours. To learn how much of a pesticide will kill fish, the researchers treat the fish with low concentrations, about what might be encountered in the water, and observe them for months to see whether they store pesticides and what effects the chemicals have on them.

Since enactment of the 1958 act, the U.S. Fish and Wildlife Service has developed a program of pesticides research at four major locations: Patuxent Wildlife Research Center, Laurel, Md.; Fish-Pesticide Laboratory, Columbia, Mo.; Denver Wildlife Research Center, Denver, Colo.; and Shellfish-Pesticide Laboratory, Gulf Breeze, Fla. Approximately 150 employees are involved in carrying out this research program of which 33 are in the Bureau of Commercial Fisheries and Wildlife. This highly trained professional staff consists of biologists, chemists, physiologists, and engineers.

Another explanation for the need of this legislation can be found in the statement at the hearings by Dr. Stanley A. Cain, Assistant Secretary of the Interior for Fish and Wildlife and Parks.

He said:

> Under the terms of the 1964 interdepartmental agreement, the Pesticide Registration Division of the Department of the Interior receives applications daily from the Department of Agriculture for registration and reregistration of pesticidal chemicals, according to provisions of the Federal Insecticide, Fungicide, and Rodenticide Act.
>
> Our staff promptly submits the conclusions of their review to USDA, advising them of any potential hazard to fish and

wildlife, and recommending any appropriate modification of label instructions or warnings. Since July 1964, when the agreement was signed, the USDA has submitted over 25,000 labels for consideration by the Interior staff. * * *

* * * * * * *

In 1958 we supported legislation authorizing pesticide research, and we supported an extension of the legislation in 1959 and 1965. A further exten[illegible] is needed because the appropriation authorization termin[illegible] on June 30, 1968. * * *

* * * * * *

Departmental scientists study the transport of pesticides, their distribution geographically and in the habitats, their degradation, and in some cases, accumulation in water and soil, and especially their biological transfer from one organism to another along the chains of the food web.

These ecological pesticide research programs can be divided into four broad categories:

1. Monitoring the levels of pesticide residues in living resources and their habitats;
2. Physiological studies of the effects of pesticides upon life processes;
3. Bioassay studies of the lethal and sublethal effects of pesticides under controlled laboratory conditions;
4. Field appraisal of the immediate and long-term effects of pesticides upon various species of fish and wildlife.

[p. 4]

Your committee noted that the President's Science Advisory Committee issued its report on the "Use of Pesticides," wherein it recommended expanded research and evaluation by the Department of the Interior of the toxic effects of pesticides on wild vertebrates and invertebrates.

Your committee further noted that the President in his message to the Congress on natural beauty of February 8, 1965, pointed to the need for increased research in pesticides and recommended the removal of the ceiling on such research. On March 8, 1968, Assistant Secretary Stanley A. Cain, in a letter to the President, recommended a draft bill which would extend the program indefinitely without a dollar ceiling.

Your committee noted that in the last 10 years the amount of expenditures for pesticide research has increased tenfold and now approximate $3 million annually. Following is a table indicating expenditures since the inception of the program.

ANNUAL EXPENDITURES FOR PESTICIDE RESEARCH—U.S. DEPARTMENT OF THE INTERIOR

[In thousands of dollars]

Year	BCF	BSFW	Total
1960	33.0	247.0	280.0
1961	95.0	291.5	386.5
1962	95.4	583.5	678.9
1963	102.2	707.6	809.8
1964	208.8	863.0	1,071.8
1965	506.3	1,822.9	2,329.2
1966	512.8	1,838.2	2,351.0
1967	732.8	2,062.9	2,795.7
1968	714.0	2,280.0	2,994.0
Total	3,000.1	10,696.6	13,696.9

The Department of the Interior witness indicated at the hearings that because of the increased need for expanded research, projected plans call for expenditures of approximately $5 million annually for the next 3 years.

In view of the foregoing, your committee unanimously recommends adoption of H.R. 15979, as amended, which would authorize to be appropriated $5 million annually for fiscal years 1969, 1970, and 1971.

WHAT THE BILL DOES—SECTION-BY-SECTION ANALYSIS

Section 1, subsection (a) of the bill, is a restatement of existing law. It would direct the Secretary of the Interior to undertake a comprehensive and continuing program of research on the effects of pesticides and other poisonous chemicals upon our Nation's fish and wildlife. The purpose of the research would be to determine amounts, percentages, and formulations of pesticidal chemicals which could be used safely, and which would prevent losses to this valuable resource.

Subsection (b) of this section would require the Secretary of the Interior to make the research information available to the Secretary of Agriculture relative to how pesticidal chemicals may be used so that injury to fish and wildlife could be prevented or minimized. It also would require the Secretary of Agriculture, in consultation with the Secretary of the Interior, to have such information appear [p. 5] on the label of each package of such chemicals which is required to be labeled under the Federal Insecticide, Fungicide, and Rodenticide Act.

In 1964, an interdepartmental agreement was entered into among the Departments of the Interior, Agriculture, and Health, Education, and Welfare, to coordinate the activities of the three Departments pertaining to pesticides. This agreement outlines the responsibilities of the respective departments which relate to the registration of pesticides and setting the tolerances for pesticide residues. Further, it requires each Department to keep each of the other Departments informed of research developments and outlines procedures for implementing interdepartmental recommendations.

Upon questioning at the hearings, the Department of Agriculture witness admitted that subsection 1(b) of section 1 of the bill would not conflict with existing practices under the law—nor under the 1964 interdepartmental agreement—nor would it in any way impinge on the capability of the Departments of the Interior and Agriculture to do precisely what they are presently doing with respect to pesticide labeling.

Over the years, your committee has witnessed an immense increase in toxicity from the use of pesticides and has heard of the widespread distribution of these chemicals without due regard to the effects on fish and wildlife. Unfortunately, it appears that the insect kingdom is holding its own while fish and wildlife are falling behind, unable to adapt to the increasingly toxic chemicals. In view of this and in view of the fact the labeling requirements of subsection (b) of section 1 of the bill are being carried out under the 1964 memorandum of understanding—which could be mutually canceled upon agreement—your committee feels that more protection would be afforded fish and wildlife by enacting into law that which is being carried out under administrative agreement. Accordingly, your committee retained this provision in the bill.

New section 2 of the 1958 act would authorize the Secretary of the Interior to conduct programs of evaluating chemicals proposed for use as pesticide chemicals to determine their potential harm to fish and wildlife resources and to distribute the results of these studies to interested people and agencies. In carrying out this provision of the legislation, the Secretary would be authorized to operate and maintain existing facilities, including laboratories.

New Section 3 of the 1958 act, as introduced, would authorize to be appropriated $5 million annually to carry out a pesticide research program indefinitely.

It was the thinking of your committee that this legislation should be limited again to a period of 3 years so that, at the termination of the program, the Congress would have an opportunity to review the needs of pesticide research.

Accordingly, your committee amended this section to authorize to be appropriated $5 million for fiscal years 1969, 1970, and 1971.

Section 2 of the bill would delay the effective date of the provisions of the bill until 180 days after enactment.

COST OF THE LEGISLATION

The maximum cost of this legislation authorized by H.R. 15979, as amended, is $5 million annually for fiscal years 1969, 1970, and 1971.

[p. 6]

DEPARTMENTAL REPORTS,
U.S. DEPARTMENT OF THE INTERIOR,
Washington, D.C., February 23, 1968.

Hon. EDWARD A. GARMATZ,
Chairman, Committee on Merchant Marine and Fisheries,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Your committee has requested this Department's report on H.R. 487, a bill to amend the act of August 1, 1958, in order to prevent or minimize injury to fish and wildlife from the use of insecticides, herbicides, fungicides, and pesticides, and for other purposes.

We recommend the enactment of H.R. 487 with the changes recommended herein.

Section 1 of the bill would amend the act of August 1, 1958 (72 Stat. 479; 16 U.S.C. 742d—1), in three ways.

The bill would add a new subsection to section 1 of the act which would require the Department to make information available to the Secretary of Agriculture relative to how pesticides, etc., may be used so that they will not injure fish or wildlife or so that the injury will be minimized. It would also require the Secretary of Agriculture to put this information on pesticide labels.

We believe that this subsection is unnecessary. The objective of the proposed subsection is the subject of administrative agreement between the Departments of Interior, Agriculture, and Health, Education, and Welfare.

The bill would add a new section 2 to the 1958 act which would authorize the Secretary to conduct programs of evaluating chemicals to determine their potential harm to fish and wildlife resources and to distribute the results of these studies to interested people and agencies.

Section 7 of the Fish and Wildlife Act of 1956 now directs the Secretary of the Interior to—

> "(4) take such steps as may be required for the development, advancement, management, conservation, and protection of the fisheries resources; and
>
> "(5) take such steps as may be required for the development, management, advancement, conservation, and protection of wildlife resources through research, acquisition of refuge lands, development of existing facilities, and other means."

In addition, section 5 of that act directs the Secretary to conduct continuing investigations and disseminate information relative to the conservation and protection of fish and wildlife.

This Department, therefore, has adequate authority under the 1956 act not only to do all that would be authorized by the new section 2 of the bill, but also to carry out a comprehensive pesticide research program. Incidentally, the Department now also has authority to conduct pesticide research in connection with our responsibilities under the Federal Water Pollution Control Act, as amended.

We recognize, however, that in 1958 we supported this legislation because it would provide the emphasis that was then and still is needed to make the public aware of the problems associated with the use of pesticides. Again in 1959 and 1965 we supported an extension of the legislation. We still strongly support the program and believe that the legislation should be extended. We believe, however, that it is not necessary to amend the 1958 act in any way except to extend it beyond June 30, 1968. This latter change is urgently needed because the appropriation authorization under the 1958 act terminates on that date. We could, of course, and would continue this important pro-

[p. 7]

gram, and seek appropriations therefor under the authority of the Fish and Wildlife Act of 1956, if action is not taken on this bill during the 90th Congress. We believe, however, that it would be better to extend the 1958 act authorization indefinitely without a dollar ceiling, as the President recommended in the 89th Congress.

The Bureau of the Budget has advised that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely yours,

CLARENCE F. PAUTZKE,
Deputy Assistant Secretary of the Interior.

DEPARTMENT OF AGRICULTURE,
Washington, D.C., February 29, 1968.

HON. EDWARD A. GARMATZ,
Chairman, Committee on Merchant Marine and Fisheries,
House of Representatives.

DEAR MR. CHAIRMAN: Thank you for your letter of January 20, 1967, giving us the opportunity to review and report on H.R. 487, a bill entitled, "To amend the act of August 1, 1958, in order to prevent or minimize injury to fish and wildlife from the use of insecticides, herbicides, fungicides, and pesticides, and for other purposes."

The bill would authorize the Secretary of the Interior to conduct a program of evaluating chemicals proposed for use as pesticides for the purpose of determining whether the chemicals are harmful or hazardous to fish and wildlife resources. It provides that on the basis of these studies, the Secretary of the Interior shall transmit information to the Secretary of Agriculture as to how injury to fish and wildlife through the use of insecticides, herbicides, fungicides, or pesticides can be prevented or minimized, and that the Secretary of Agriculture shall require such information or warning to appear on the label of each package of such insecticide, herbicide, fungicide, or pesticide under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act. The bill further provides that the Secretary of the Interior would distribute, to interested persons and agencies, both public and private, data collected showing the effects of pesticides and would authorize him to operate and maintain facilities necessary to carry out the purposes of the bill. H.R. 487 also would authorize the appropriation of the necessary funds to carry out its purposes. The proposed amendments would be effective 180 days after the bill's enactment.

This Department has no objection to the proposed bill to the extent that it would provide new and more extensive research data on the relation of pesticides to fish and wildlife and increased information to this Department for use in the administration of the Federal Insecticide, Fungicide, and Rodenticide Act. However, we defer to the Department of the Interior as to the need for this provision.

The provisions of that part of the proposed amendment dealing with the labeling of products registered under the Federal Insecticide, Fungicide, and [p. 8] Rodenticide Act would appear to create the possibility of a conflict of authority between the Secretary of Agriculture and the Secretary of the Interior in the administration of the act. Further, these provisions are being carried out administratively through an interdepartmental agreement among the Departments of Health, Education, and Welfare; the Interior; and Agriculture developed as a result of the President's Science Advisory Committee report on the "Use of Pesticides."

Therefore, this Department recommends against section 1 (b) of H.R. 487.

The Bureau of the Budget advises that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely yours,

ORVILLE L. FREEMAN, *Secretary*.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., February 26, 1968.

HON. EDWARD A. GARMATZ,
Chairman, Committee on Merchant Marine and Fisheries,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of January 20, 1967, for a report on H.R. 487, a bill to amend the act of August 1, 1958, in order to prevent or minimize injury to fish and wildlife from the use of insecticides, herbicides, fungicides, and pesticides and for other purposes.

Section 1 of H.R. 487 would require the Secretary of the Interior, on the basis of studies of the effects of insecticides, herbicides, fungicides, or pesticides on fish and wildlife, to transmit to the Secretary of Agriculture information as to how, in the use of such chemicals, injury to fish and wildlife can be prevented or minimized. The Secretary of Agriculture, in consultation with the Secretary of the Interior, would be required to have such information appear on the label of each package of pesticides which is required to be labeled under the Federal Insecticide, Fungicide, and Rodenticide Act.

Section 2 of H.R. 487 would authorize the Secretary of the Interior to conduct a program of evaluating chemicals proposed for use as pesticides, to determine whether the chemicals are harmful or hazardous to fish and wildlife; to distribute data showing the effects of pesticides on fish and wildlife; and to operate and maintain facilities necessary to these purposes. It also provides for an increase in the present appropriations ceiling for the Department of Interior.

We are in accord with the objectives of this bill to give due consideration to the interests of conservation of fish and wildlife in the regulation of pesticides. However, due consideration should be given also to the harmful or hazardous effects of pesticides on humans, domestic animals, and agricultural crops. We believe, however, that section 1 of the bill, in regard to labeling, is unnecessary. In 1964 an interdepartmental agreement was entered into between the Departments of Agriculture, Interior, and Health, Education, and Welfare to coordinate the activities of the three Departments pertaining to pesticides. This agreement outlines the responsibilities of the respective [p. 9] Departments which relate to the registration of pesticides and the setting of tolerances for pesticide residues. The agreement further provides that each Department will undertake to keep each of the other Departments fully informed of developments in knowledge on this subject from research or other sources which may come into its possession. The agreement also outlines the procedures to implement these interdepartmental coordination procedures. This interdepartmental agreement is intended to provide a mechanism for the efficient coordination of matters relating to pesticides which section 1 of H.R. 487 undertakes to remedy. A copy of this agreement is attached for your information.

We defer to the views of the Department of the Interior with respect to section 2 of the bill.

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely,

WILBUR J. COHEN,
Under Secretary.

MEMORANDUM OF AGREEMENT BETWEEN THE DEPARTMENT OF AGRICULTURE, THE DEPARTMENT OF THE INTERIOR, AND THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON INTERDEPARTMENTAL COORDINATION OF ACTIVITIES RELATING TO PESTICIDES

PURPOSE

Coordination of activities of the three Departments pertaining to pesticides with special reference to registration and the setting of tolerances to give effect to the pertinent recommendations of the May 15, 1963, report of the President's Science Advisory Committee on "Use of Pesticides."

EXISTING DEPARTMENTAL RESPONSIBILITIES

The following responsibilities of the respective departments relate to the registration of pesticides and the setting of tolerances for pesticide residues:

Department of the Interior

Fish and Wildlife Service.—Conserving beneficial wild birds, mammals, fish and their food organisms and habitat, with regard to pesticides.

Department of Health, Education, and Welfare

U.S. Public Health Service.—Protecting and improving the health of man in regard to pesticides.

Food and Drug Administration.—Establishing tolerances for pesticides in or on raw agricultural commodities and processed foods.

Department of Agriculture

Agricultural Research Service.—Providing for the safe and effective use of pesticides, including the registration thereof.

[p. 10]

AGREEMENT

1. Information

Each department undertakes to keep each of the other departments fully informed of developments in knowledge on this subject from research or other sources which may come into its possession. Additionally, the Department of Agriculture undertakes to furnish to the other two departments on a weekly basis a listing of all proposals affecting registration and re-registration, and the Department of Health, Education, and Welfare undertakes to furnish to the other two departments on a weekly basis a listing of all proposals affecting tolerances. Upon request, the Departments of Agriculture and Health, Education, and Welfare respectively will furnish to the other departments full information about any pending action on registration or the setting of a tolerance.

2. Procedure

(a) Each department will designate a scientist to act on behalf of such department in carrying out the terms of this agreement. The weekly listings from the Departments of Agriculture and Health, Education, and Welfare and any additional information relating thereto will be directed to these representatives.

(b) The departmental representative will review the weekly listings of actions pending. If there is reason to question any of the items on that list, this will be communicated to the originating department within 1 week stating the specific reason for need for further review.

(c) Upon receipt of such request the originating department will furnish the necessary information and make the necessary arrangements for further review and will withhold final action on the matter for an additional 3 weeks.

(d) If one department concludes that the proposal should be rejected in whole or in part, this view shall be expressed in writing and shall be supported by appropriate scientific evidence. Upon being notified, the department responsible for final action will take the initiative to work out a basis for agreement.

(e) In the event agreement is not reached among the depart-

ment representatives within 2 weeks of the initial objection, the matter will then be referred directly to the Secretary of the department responsible for final action with such information, views, and recommendations as the three department representatives deem appropriate.

(f) The Secretary of the Department charged with final action may then avail himself of whatever administrative and scientific review procedures seem appropriate under the circumstances. The other two Departments will be notified in advance of the proposed final determination of the issues.

(g) The Department representatives will jointly make a quarterly report concerning their activities to the Secretaries of the three Departments.

(h) The departmental representatives are authorized to review questions involving existing patterns of use of pesticides or tolerances upon which they have reason to believe that critical questions exist.

3. Conference

At least once each year the departmental representatives will arrange a general conference to discuss research needs, research [p. 11] program and policy, and the application of research findings in action programs, including public information relating to pesticides.

4. Federal Pest Control Review Board

The Federal Pest Control Review Board may be asked from time to time to consider broad questions on policies relating to pesticides involving the interrelationships of control programs, research, registration, tolerances, and general departmental recommendations to the public.

ORVILLE L. FREEMAN,
Secretary, Department of Agriculture
Dated April 8, 1964.

STEWART L. UDALL,
Secretary, Department of the Interior
Dated March 27, 1964.

ANTHONY J. CELEBREZZE,
Secretary, Department of Health, Education, and Welfare
Dated April 3, 1964.

CHANGES IN EXISTING LAW

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, as amended, changes in existing law made by the bill as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Act of August 1, 1958

(16 U.S.C. 742d-1)

[That the Secretary of the Interior is authorized and directed to undertake comprehensive continuing studies on the effects of insecticides, herbicides, fungicides, and pecticides, upon the fish and wildlife resources of the United States, for the purpose of determining the amounts, percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and the amounts, percentages, mixtures, or formulations that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting, or other treatment.

[SEC. 2. In order to carry out the provisions of this Act, there are authorized to be appropriated for the fiscal year ending June 30, 1966, not to exceed $3,200,000, and not to exceed $5,000,000 for each of the two fiscal years immediately following such year.]

That (a) the Secretary of the Interior is authorized and directed to undertake comprehensive continuing studies on the effects of insecticides, herbicides, fungicides, and pesticides, upon the fish and wildlife resources of the United States, for the purpose of determining the amounts, percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and the amounts, percentages, mixtures, or formulations that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting, or other treatment.

(b) On the basis of the studies carried on pursuant to subsection (a) of this section, the Secretary of the Interior shall transmit in- [p. 12] *formation to the Secretary of Agriculture as to how, in the use of insecticides, herbicides, fungicides, or other pesticides, injury to fish and wildlife can be prevented or minimized and the Secretary of Agriculture, in consultation with the Secretary of the Interior, shall require that such information or warning pertinent to any insecticide, herbicide, fungicide, or other pesticide shall appear on the label of each package of such insecticide, herbicide, fungicide, or other pesticide, as the case may be, which is required to be labeled under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135–135k).*

SEC. *2. The Secretary of the Interior is authorized—*

(1) to conduct a program of evaluating chemicals proposed for use as insecticides, herbicides, fungicides, or other pesti-

cides for the purposes of determining whether the chemicals are harmful or hazardous to the Nation's fish and wildlife resources;

(2) to distribute to interested persons and agencies, both public and private, data collected under this Act showing the effects of insecticides, herbicides, fungicides, or other pesticides; and

(3) to operate and maintain existing facilities, including laboratories, necessary to carry out the purposes of this Act.

SEC. *3. There is authorized to be appropriated the sum of $5,000,000 for the fiscal year ending June 30, 1969, and for each of the two fiscal years immediately following such year.*

NOTE.—The amendments made by this Act shall take effect on the one hundred and eightieth day after the date of enactment of this Act.

[p. 13]

1.3d (2) SENATE COMMITTEE ON COMMERCE

S. REP. No. 1236, 90th Cong., 2d Sess. (1968)

EFFECTS OF PESTICIDES UPON FISH AND WILDLIFE

JUNE 13, 1968.—Ordered to be printed

Mr. MAGNUSON, from the Committee on Commerce, submitted the following

REPORT

together with

INDIVIDUAL VIEWS

[To accompany H.R. 15979]

The Committee on Commerce, to which was referred the bill (H.R. 15979) to amend the act of August 1, 1958, in order to prevent or neutralize injury to fish and wildlife from the use of pesticides, herbicides, fungicides, and pesticides, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill, as amended, do pass.

PURPOSE OF THE BILL

The purpose of the bill, as amended, is to continue the comprehensive continuing study of the effects of pesticides upon fish and wildlife resources, which was authorized in the act of August 1, 1958, as amended, by authorizing annual appropriations under that act not to exceed $3,500,000 in each of fiscal years 1969, 1970, and 1971.

LEGISLATIVE BACKGROUND

Through enactment of the Pesticides Research Act in 1958, Congress directed the Secretary of the Interior through the Fish and Wildlife Service to undertake comprehensive continuing studies of the effects of pesticides upon fish and wildlife resources for the purpose of determining the amounts and formulations of such chemicals that are lethal or injurious to such resources and the amounts or mixtures that can be used safely so as to prevent loss of fish and wildlife from dusting, spraying, or other use of chemicals. [p. 1]

Under that act, the Fish and Wildlife Service has developed a program of pesticides research at five major locations: Patuxent Wildlife Research Center, Laurel, Md.; Fish-Pesticide Laboratory, Columbia, Mo.; Denver Wildlife Research Center, Denver, Colo.; Shellfish-Pesticide Laboratory, Gulf Breeze, Fla.; and Biological Laboratory, Ann Arbor, Mich. Approximately 150 employees are involved in carrying out this research program of which 34 are in the Bureau of Sports Fisheries and Wildlife. This highly trained professional staff consists of biologists, chemists, physiologists, and engineers.

The results of these research programs are currently being transmitted to the Department of Agriculture pursuant to a formal memorandum of agreement entered into in 1964 by the Department of the Interior, the Department of Agriculture, and the Department of Health, Education, and Welfare.

Under the terms of that agreement, the Pesticides Registration Division of the Department of the Interior receives applications daily from the Department of Agriculture for registration of pesticidal chemicals required by the Federal Insecticide, Fungicide, and Rodenticide Act administered by the Department of Agriculture. (7 U.S.C. 135–135k).

The Pesticides Registration Division of the Department of the Interior then submits the conclusions of their review of these applications to the Department of Agriculture advising it of any potential hazard to fish and wildlife, and recommending any appropriate modification of label instructions or warning on the particular pesticidal chemical.

The Department of the Interior, through the Fish and Wildlife Service, carries out a number of cooperative studies leading to the discovery and development of more selective and less hazardous pest control methods; and many other extensive research programs designed to evaluate the potentially injurious effects of various pesticides on fish and wildlife.

NEED FOR THE LEGISLATION

The amount of pesticidal chemicals being produced and used increases yearly. In 1964, the U.S. chemical industry produced 783 million pounds of pesticides, of which three-quarters were for domestic use. In 1967, in the United States alone, 10,000 manufacturing firms mixed more than 900 chemical compounds into over 60,000 formulations registered with the Department of Agriculture for use as pesticides. Sales increased an estimated 12 percent in 1967 over 1966, and, by 1985, it is estimated they will increase another sixfold.

It has been reported that about 1 acre in every 10 in the continental United States is treated annually with an average of nearly 4 pounds of pesticides. Most of the pesticides are used on the farm. Fifteen percent of the 460 million acres of farmland in the United States—69 million acres—produces crops requiring insecticides—corn, rice, cotton, vegetables, fruits, and nuts.

Some pesticides have traveled great distances from actual use and persisted for long periods of time. Air currents, water runoff, dust particles, and living organisms have been their vehicles. Residues have even been found in penguins and crab-eater seals in Antarctica. DDT was found in the oil of fish that live far from land and in those caught off the coasts of four continents—ranging in [p. 2] concentrations from less than one part of DDT in 1 million parts of oil (one part per million) to more than 300 parts per million. Often, fish do not die immediately or at the site of the pesticide exposure. In one recorded case, fish started dying 3 months after DDT was applied, and death reached downstream nearly 100 miles from the treatment site.

From 1960 to 1963, of 56 bald eagles found dead or incapacitated in 20 States and two Canadian Provinces, all but one (from Alaska) contained DDT.

The U.S. Public Health Service has reported traces of one or more chlorinated hydrocarbons in every major river system in the Nation.

Pesticides are particularly significant to the fishing industry. Some of the most valuable species of fish and shellfish are also the most sensitive to pesticides. Ten marine animal groups make up 80 percent of the $381.2 million fishing industry of the United States. Of the 10, five spend important parts of their lives in estuarine waters (where salt and fresh water meet) and are vulnerable to pesticides. The five are shrimp, mollusks, Pacific salmon, crabs, and menhaden (a member of the herring family used to make poultry feeds and oil).

During the past 4 years, Fish and Wildlife Service researchers have developed objective methods for measuring effects of pesticides. New chemicals sent by manufacturers are tested on plankton, shrimp, crabs, oysters, and one or two species of commercial fish. The researchers seek to assist in finding narrow-spectrum pesticides that may be used to control target pests without harm to other life.

Some pesticides paralyze shrimp or other crustaceans rather than kill them. The criteria for testing toxicity of this group are set by learning the concentrations of pesticide that will cause paralysis or death to half of the sample within 24 to 48 hours. To learn how much of a pesticide will kill fish, the researchers treat the fish with low concentrations, about what might be encountered in the water, and observe them for months to see whether they store pesticides and what effects the chemicals have on them.

Your committee has been further advised by the Department of the Interior that studies of the past few years have highlighted three types of research priorities:

1. *Residue levels in animal bodies that indicate hazards to normal reproduction and behavior.*—Experimental studies especially designed to determine quantities of pesticides in wild animals and their environments are necessary. Toxic limits should be established for the various chlorinated hydrocarbons and heavy metals (lead, mercury) found in animal tissues, together and separately. Variations in toxicity due to species differences in sensitivity, and variations due to stresses on individuals should be determined.

2. *Quantities of residues in the fish and wildlife environment.*—This would supplement the general information obtained in the national monitoring program. The environments of declining species such as golden eagles, pelicans, ospreys, and of truly rare and endangered species such as the southern bald eagle should be studied. Estuarine areas, inland waters, forests, and grazing lands —all historically have supported significant wildlife populations. Perceptive investigations there should focus on residues in the major animals and the food organisms in these habitats.

[p. 3]

3. *Changes and flows of residue levels.*—Rates and pathways of gain and loss in various wild animals and their environments should be identified. New chemical factors have been entering the

lives and habitats of animals in recent years. Where they come from, where they go, and hazards or lack of hazards they pose while residing in wildlife need to be learned.

HEARINGS AND COMMITTEE CONSIDERATION OF THE BILL

H.R. 15979, as it passed the House of Representatives, would restate the Pesticides Research Act of 1958.

In addition, it would add a new subsection 1(b) to that law requiring the Secretary of the Interior to make research information available to the Secretary of Agriculture as to how in the use of pesticidal chemicals injury to fish and wildlife can be prevented or minimized. The Secretary of Agriculture, after consultation with the Secretary of the Interior, would then be required to have such information appear on the label of each package of pesticides required to be labeled under the Federal Insecticide, Fungicide, and Rodenticide Act.

The bill would also add a new section 2 to the existing law authorizing the Secretary of the Interior to conduct programs of evaluating chemicals proposed for use as pesticide chemicals to determine their potential harm to fish and wildlife resources and to distribute the results of these studies to interested people and agencies.

Under the bill, as approved by the House, $5 million annually would be authorized to be appropriated for fiscal years 1969, 1970, and 1971. However, the provisions of the bill including the authorization would not become effective until 180 days after its enactment.[1]

Hearings on H.R. 15979 were held on May 17 of this year. Your committee heard extensive testimony from the Department of the Interior, the Department of Agriculture, and other interested witnesses. All favored the continuation of the comprehensive pesticides research program being carried out under the Pesticides Research Act of 1958. The Department of the Interior urged that the authorization provision be amended to become effective July 1, 1968. Otherwise there would be a hiatus in the programs carried out under that act, because the current authorization for funds expires on June 30, 1968.

The Department of Agriculture opposed the labeling provision of new subsection 1(b) because it felt it would appear to conflict with the authority of the Secretary of Agriculture in the administration of the Federal Insecticide, Fungicide, and Rodenticide Act. And further, that the objectives of subsection 1(b) are now accomplished under the interdepartmental agreement among the Departments of Agriculture, Interior, and Health, Education, and Welfare.

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[1] S. 3228 (introduced by request of the Department of the Interior by Senator Magnuson) would have extended the authorization for appropriations under the act of Aug. 1, 1958, for fiscal year 1969 and each succeeding fiscal year such sums as may be necessary to carry out the purposes of that act.

It was strongly supported in its opposition to subsection 1(b) by the National Agricultural Chemicals Association.

The National Wildlife Federation and a number of conservation groups, on the other hand, favored the labeling provision contending that the final authority should rest with the Secretary of the Interior for determining whether information concerning the dan- [p. 4] ger of potential injury of a particular pesticide to fish and wildlife should appear on the label of that pesticide.

In this connection, your committee particularly noted the testimony of the Department of the Interior. Although it did not urge enactment of subsection 1(b), the Department of the Interior did state that its pesticidal research program is centered on evaluating possible pesticidal side effects on the numerous species of fish and wildlife and their necessary foods and environments. Consequently its program used different techniques and approaches than the research program carried out by the Department of Agriculture which concentrates its studies primarily on target pests.

Most of the witnesses testified that the successful operation of the interdepartmental agreement achieved through the effective cooperation of the departments involved makes additional statutory authority unnecessary at this time.

On the contrary, the two Departments affected testified that the existing interdepartmental agreement accomplishes the same result and was working effectively. In 1967, for example, a total of 6,544 label proposals under the Federal Insecticide, Fungicide, and Rodenticide Act were referred to the Department of the Interior by the Department of Agriculture pursuant to the interdepartmental agreement. Where the Department of the Interior provided additional advice concerning these referrals, the Department of Agriculture concurred in all but five or six.

Accordingly, H.R. 15979 has been amended by striking the proposed subsection 1(b).

Your committee also felt section 2 of H.R. 15979 should be amended so that it would become effective immediately upon enactment. Accordingly, that provision was also deleted. The amounts authorized to be appropriated for fiscal years 1969, 1970, and 1971 were also revised downward to $3.5 million annually.

The testimony heard was unanimous in support of the present continuing pesticidal research program being carried out by the Department of the Interior under the Pesticides Research Act. Since the authorization for funds under that act expires at the end of fiscal 1968, unless the new authorization becomes effective upon enactment of H.R. 15979, the program would be halted, at least temporarily.

H.R. 15979, as approved by the House of Representatives, contained a 3-year $5 million annual authorization ceiling. As amended, by your committee, the annual ceiling for the fiscal years 1969, 1970, and 1971 would be $3.5 million. It is felt that this amount while providing room for growth, more accurately reflects the need for annual appropriations and expenditures for the program.

That part of H.R. 15979 which restates the act of August 1, 1958, has been deleted as unnecessary.

Similarly, your committee has deleted that provision in H.R. 15979 which would have added a provision to the Pesticides Research Act authorizing the Secretary of the Interior to conduct programs of evaluating the effects of pesticidal chemicals to determine their potential harm to fish and wildlife, and to distribute this material to interested persons and agencies, It was felt that what this section would require is currently authorized under existing law.

[p. 5]

Finally, the title of H.R. 15979 has been amended to reflect more accurately what effect the bill has on the act of August 1, 1958.

CONCLUSION

According to the President's Science Advisory Committee, the worldwide use of pesticides will grow from 120,000 metric tons per year to 700,000 metric tons because the overall amount of poisons needed to control pests will grow with the increasing demand for food and fiber.

It seems evident that such massive applications of pesticides will have a profound effect on other living organisms, including fish and wildlife. It is, therefore, important that every possible precaution be taken to minimize damages to these living resources. Continued and comprehensive research of the kind now being carried out by the Department of the Interior and precautionary measures will be assured by enactment of this legislation.

[p. 6]

INDIVIDUAL VIEWS OF MESSRS. HART AND MAGNUSON

The emphasis and techniques of the Department of the Interior in pesticidal research are directed specifically toward danger to fish and wildlife, whereas the Department of Agriculture specifically seeks to identify protection of crops and elimination of pests. I believe the action of the House in adding subsection 1(b) was wise and I oppose the elimination of this labeling provision. The fact that the Department of Agriculture concurred with the Department of the Interior in all but five or six of more than 6,500 label proposals in 1967, does not persuade me that subsection 1 (b) is unnecessary. These five or six instances can be said to support the desirability that when danger to fish and wildlife is identified by Interior, the law should require that such information appear on the labels of the pesticide in question.

[p. 15]

CHANGES IN EXISTING LAW

In compliance with subsection 4 of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

ACT OF AUGUST 1, 1958

(72 Stat. 479, as amended, 79 Stat. 902)

[SEC. 2. In order to carry out the provisions of this Act, there is authorized to be appropriated for the fiscal year ending June 30, 1966, not to exceed $3,200,000, and not to exceed $5,000,000 for each of the two fiscal years immediately following such year.]

SEC. 2. *In order to carry out the provisions of this Act, there is authorized to be appropriated the sum of $3,500,000 for the fiscal year ending June 30, 1969, and for each of the two fiscal years immediately following such year. Such sums shall remain available until expended.*

[p. 16]

1.3d (3) CONGRESSIONAL RECORD, VOL. 114 (1968)

1.3d (3) (a) June 24: Passed Senate, pp. 18356–18357

MINIMIZING INJURY TO FISH AND WILDLIFE

Mr. MANSFIELD. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 1213, H.R. 15979.

The PRESIDING OFFICER. The bill will be stated by title.

The LEGISLATIVE CLERK. H.R. 15979, to amend the act of August 1, 1958, in order to prevent or minimize injury to fish and wildlife from the use of insecticides, herbicides, fungicides, and pesticides, and for other purposes.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Commerce, with an amendment, to strike out all after the enacting clause and insert:

SEC. 2. In order to carry out the provisions of this Act, there is authorized to be appropriated the sum of $3,500,000 for the fiscal year ending June 30, 1969, and for each of the two fiscal years immediately following such year. Such sums shall remain available until expended.

The PRESIDING OFFICER. The question is on agreeing to the amendment.

The amendment was agreed to.

The amendment was ordered to be engrossed and the bill to be read a third time.

The bill was read the third time and passed.

The title was amended, so as to read: "An act to amend section 2 of the act of August 1, 1958, as amended in order to prevent or minimize injury to fish and wildlife from the use of insecticides, herbicides, fungicides, and other pesticides."

Mr. MANSFIELD. Mr. President, I ask unanimous consent to have printed in the RECORD an excerpt from the report (No. 1236), explaining the purposes of the bill.

[p. 18356]

There being no objection, the excerpt was ordered to be printed in the RECORD, as follows:

* * * * *

[p. 18357]

1.3d (3) (b) June 27: Passed House, p. 19095

Mr. DINGELL. Mr. Speaker, I ask unanimous consent to take from the Speaker's desk the bill (H.R. 15979) to amend the act of August 1, 1958, in order to prevent or minimize injury to fish and wildlife from the use of insecticides, herbicides, fungicides, and pesticides, and for other purposes, with Senate amendments thereto, and concur in the Senate amendments.

* * * * *

The SPEAKER. Is there objection to the request of the gentleman from Michigan?

Mr. GROSS. Mr. Speaker, reserving the right to object, I would ask the gentleman from Michigan whether the Senate amendments are germane to the bill?

Mr. DINGELL. If the gentleman will yield, I would say that all amendments are germane.

Mr. GROSS. How did the House come out financially?

Mr. DINGELL. If the gentleman will yield further, I will be most pleased to answer the gentleman from Iowa.

The House bill provided $5 million over a period of 3 fiscal years. The Senate bill provided $3.5 million over the same 3 fiscal years, which was a cut of $1.5 million per fiscal year.

The Senate struck out the labeling requirements that had been inserted in the House. So that all that remains is the authorization to spend $3.5 million a year for each of three fiscal years in extension of an existing program which passed this House in years past unanimously, without the labeling requirements which had been in the bill.

Mr. GROSS. Mr. Speaker, I thank the gentleman from Michigan for his explanation, and withdraw my reservation of objection.

The SPEAKER. Is there objection to the request of the gentleman from Michigan?

There was no objection.

The Senate amendments were concurred in.

A motion to reconsider was laid on the table.

[p. 19095]

1.4 PUBLIC HEALTH SERVICE ACT, AS AMENDED

42 U.S.C. §§241, 243, 246, 264 (1970),

(See, "General 1.12a–1.12ae (3) (c)" for legislative history)

PART A.—RESEARCH AND INVESTIGATIONS

§ 241. Research and investigations generally

The Surgeon General shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Surgeon General is authorized to—

(a) Collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(b) Make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(c) Establish and maintain research fellowships in the Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad;

(d) Make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research or research training projects as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Advisory Cancer Council, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or, with respect to heart diseases recommended by the National Advisory Heart Council or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research and research training programs: *Provided,* That such uniform percentage, not to exceed 15 per centum, as the Surgeon General may determine, of the amounts provided for grants for research or research training projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research and research training program grants-in-aid for such fiscal year;

(e) Secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(f) For purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(g) Make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(h) Enter into contracts during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of Title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; and

(i) Adopt, upon recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Advisory Cancer Council, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart diseases, upon recommendation of the National Advisory Heart Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems necessary or appropriate to carry out the purposes of this section.

July 1, 1944, c. 373, Title III, § 301, 58 Stat. 691; July 3, 1946, c. 538, § 7(a, b), 60 Stat. 423; June 16, 1948, c. 481, § 4(e, f), 62 Stat. 467; June 24, 1948, c. 621, § 4(e, f), 62 Stat. 601; June 25, 1948, c. 654, § 1, 62 Stat. 1017; July 3, 1956, c. 510, § 4, 70 Stat. 490; Sept. 15, 1960, Pub.L. 86–798, 74 Stat. 1053; Oct. 17, 1962, Pub.L. 87–838, § 2, 76 Stat. 1073; Aug. 9, 1965, Pub.L. 89–115, § 3, 79 Stat. 448; Dec. 5, 1967, Pub.L. 90–174, § 9, 81 Stat. 540; and amended Oct. 30, 1970, Pub.L. 91–515, Title II, § 292, 84 Stat. 1308.

Part B.—Federal-State Cooperation

§ 243. General grant of authority for cooperation—Enforcement of quarantine regulations; prevention of communicable diseases

(a) The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this chapter which such authorities may be able and willing to provide. The Secretary shall also assist States and their political subdivisions in the prevention and suppression of communicable diseases, shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations and in carrying out the purposes specified in section 246 of this title, and shall advise the several States on matters relating to the preservation and improvement of the public health.

Comprehensive and continuing planning; training of personnel for State and local health work

(b) The Secretary shall encourage cooperative activities between the States with resepct to comprehensive and continuing planning as to their current and future health needs, the establishment and maintenance of adequate public health services, and otherwise carrying out the purposes of section 246 of this title. The Secretary is also authorized to train personnel for State and local health work.

Problems resulting from disasters; emergencies; reimbursement of United States

(c) The Secretary may enter into agreements providing for cooperative planning between Public Health Service medical facilities and community health facilities to cope with health problems resulting from disasters, and for participation by Public Health Service medical facilities in carrying out such planning. He may also, at the request of the appropriate State or local authority, extend temporary (not in excess of forty-five days) assistance to States or localities in meeting health emergencies of such a nature as to warrant Federal assistance. The Secretary may require such reimbursement of the United States for aid (other than planning) under the preceding sentences of this subsection as he may determine to be reasonable under the circumstances. Any reimbursement so paid shall be credited to the applicable appropriation of the Public Health Service for the year in which such reimbursement is received.

July 1, 1944, c. 373, Title III, § 311, 58 Stat. 693; Nov. 3, 1966, Pub.L. 89–749, § 5, 80 Stat. 1190; Dec. 5, 1967, Pub.L. 90–174,

§ 4, 81 Stat. 536; and amended Oct. 30, 1970, Pub.L. 91-515, Title II, § 282, 84 Stat. 1308.

§ 246. Grants and services to States—Comprehensive health planning and services

(a) (1) In order to assist the States in comprehensive and continuing planning for their current and future health needs, the Secretary is authorized during the period beginning July 1, 1966, and ending June 30, 1973, to make grants to States which have submitted, and had approved by the Secretary, State plans for comprehensive State health planning. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $2,500,000 for the fiscal year ending June 30, 1967, $7,000,000 for the fiscal year ending June 30, 1968, $10,000,000 for the fiscal year ending June 30, 1969, $15,000,000 for the fiscal year ending June 30, 1970, $15,000,000 for the fiscal year ending June 30, 1971, $17,000,000 for the fiscal year ending June 30, 1972, and $20,000,000 for the fiscal year ending June 30, 1973.

(2) In order to be approved for purposes of this subsection, a State plan for comprehensive State health planning must—

(A) designate, or provide for the establishment of, a single State agency, which may be an interdepartmental agency, as the sole agency for administering or supervising the administration of the State's health planning functions under the plan;

(B) Provide for the establishment of a State health planning council, which shall include representatives of Federal, State, and local agencies (including as an ex officio member, if there is located in such State one or more hospitals or other health care facilities of the Veterans' Administration, the individual whom the Administrator of Veterans' Affairs shall have designated to serve on such council as the representative of the hospitals or other health care facilities of such Administration which are located in such State) and nongovernmental organizations and groups concerned with health, (including representation of the regional medical program or programs included in whole or in part within the State) and of consumers of health services, to advise such State agency in carrying out its functions under the plan, and a majority of the membership of such council shall consist of representatives of consumers of health services;

(C) set forth policies and procedures for the expenditure of funds under the plan, which, in the judgment of the Secretary are designed to provide for comprehensive State planning for health services (both public and private) and including home health care, including the facilities and persons required for the provision of such services, to meet the health needs of the people of the State and including environmental considerations as they relate to public health;

(D) provide for encouraging cooperative efforts among governmental or nongovernmental agencies, organizations and groups concerned with health services, facilities, or manpower, and for cooperative efforts between such agencies, organizations, and groups and similar agencies, organizations, and groups in the fields of education, welfare, and rehabilitation;

(E) contain or be supported by assurances satisfactory to the Secretary that the funds paid under this subsection will be used to supplement and, to the extent practicable, to increase the level of funds that would otherwise be made available by the State for the purpose of comprehensive health planning and not to supplant such non-Federal funds;

(F) provide such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods) as are found by the Secretary to be necessary for the proper and efficient operation of the plan;

(G) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of such reports;

(H) provide that the State agency will from time to time, but not less often than annually, review its State plan approved under this subsection and submit to the Secretary appropriate modifications thereof;

(I) effective July 1, 1968, (i) provide for assisting each health care facility in the State to develop a program for capital expenditures for replacement, modernization, and expansion which is consistent with an overall State plan developed in accordance with criteria established by the Secretary after consultation with the State which will meet the needs of the State for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner, and (ii) provide that the State agency furnishing such assistance will periodically review the program (developed pursuant to clause (i)) of each health care facility in the State and recommend appropriate modification thereof;

(J) provide for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for funds paid to the State under this subsection; and

(K) contain such additional information and assurances as the Secretary may find necessary to carry out the purposes of this subsection.

(3) (A) From the sums appropriated for such purpose for each fiscal year, the several States shall be entitled to allotments determined, in accordance with regulations, on the basis of the population and the per capita income of the respective States; except that no such allotment to any State for any fiscal year shall be less than 1 per centum of the sum appropriated for such fiscal year pursuant to paragraph (1). Any such allotment to a State for fiscal year shall remain available for obligation by the State, in accordance with the provisions of this subsection and the State's plan approved thereunder, until the close of the succeeding fiscal year.

(B) The amount of any allotment to a State under subparagraph (A) for any fiscal year which the Secretary determines will not be required by the State, during the period for which it is available, for the purposes for which alloted shall be available for reallotment by the Secretary from time to time, on such date or dates as he may fix, to other States with respect to which such a determination has not been made, in proportion to the original allotments to such States under subparagraph (A) for such fiscal year, but with such proportionate amount for any of such other States being reduced to the extent it exceeds the sum the Secretary estimates such State needs and will be able to use during such period; and the total of such reductions shall be similarly reallotted among the States whose proportionate amounts were not so reduced. Any amount so reallotted to a State from funds appropriated pursuant to this subsection for a fiscal year shall be deemed part of its allotment under subparagraph (A) for such fiscal year.

(4) From each State's allotment for a fiscal year under this subsection, the State shall from time to time be paid the Federal share of the expenditures incurred during that year or the succeeding year pursuant to its State plan approved under this sub-

section. Such payments shall be made on the basis of estimates by the Secretary of the sums the State will need in order to perform the planning under its approved State plan under this subsection, but with such adjustments as may be necessary to take account of previously made underpayments or overpayments. The "Federal share" for any State for purposes of this subsection shall be all, or such part as the Secretary may determine, of the cost of such planning, except that in the case of the allotments for the fiscal year ending June 30, 1970, it shall not exceed 75 per centum of such cost.

Project grants for areawide health planning; authorization of appropriations; prerequisites for grants; application; contents

(b) (1) (A) The Secretary is authorized, during the period beginning July 1, 1966, and ending June 30, 1973, to make, with the approval of the State agency administering or supervising the administration of the State plan approved under subsection (a) of this section, project grants to any other public or nonprofit private agency or organization (but with appropriate representation of the interests of local government where the recipient of the grant is not a local government or combination thereof on an agency of such government or combination) to cover not to exceed 75 per centum of the cost of projects for developing (and from time to time revising) comprehensive regional, metropolitan area, or other local area plans for coordination of existing and planned health services, including the facilities and persons required for provision of such services; and including the provision of such services through home health care except that in the case of project grants made in any State prior to July 1, 1968, approval of such State agency shall be required only if such State has such a State plan in effect at the time of such grants. No grant may be made under this subsection after June 30, 1970, to any agency or organization to develop or revise health plans for an area unless the Secretary determines that such agency or organization provides means for appropriate representation of the interests of the hospitals, other health care facilities, and practicing physicians serving such area, and the general public. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $5,000,000 for the fiscal year ending June 30, 1967, $7,500,000 for the fiscal year ending June 30, 1968, $10,000,000 for the fiscal year ending June 30, 1969, $15,000,000 for the fiscal year ending June 30, 1970, $20,000,000 for the fiscal year ending June 30, 1971, $30,000,000 for the fiscal year ending June 30, 1972, and $40,000,000 for the fiscal year ending June 30, 1973.

(B) Project grants may be made by the Secretary under subparagraph (A) to the State agency administering or supervising the administration of the State plan approved under subsection (a) of this section with respect to a particular region or area, but only if (i) no application for such a grant with respect to such region or area has been filed by any other agency or organization qualified to receive such a grant, and (ii) such State agency certifies, and the Secretary finds, that ample opportunity has been afforded to qualified agencies and organizations to file application for such a grant with respect to such region or area and that it is improbable that, in the foreseeable future, any agency or organization which is qualified for such a grant will file application therefor.

(2) (A) In order to be approved under this susbection, an application for a grant under this subsection must contain or be supported by reasonable assurances that there has been or will be established, in or for the area with respect to which such grant is sought, an areawide health planning council. The membership of such council shall include representatives of public, voluntary, and nonprofit private agencies, institutions, and organizations concerned with health (including representatives of the interests of local government, of the regional medical program for such areas, and of consumers of health services). A majority of the members of such council shall consist of representatives of consumers of health services.

(B) In addition, an application for a grant under this subsection must contain or be supported by reasonable assurances that the areawide health planning agency has made provision for assisting health care facilities in its area to develop a program for capital expenditures for replacement, modernization, and expansion which is consistent with an overall State plan which will meet the needs of the State and the area for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner.

Project grants for training, studies, and demonstrations; authorization of appropriations

(c) The Secretary is also authorized, during the period beginning July 1, 1966, and ending June 30, 1973, to make grants to any public or nonprofit private agency, institution, or other organization to cover all or any part of the cost of projects for training, studies, or demonstrations looking toward the development of improved or more effective comprehensive health planning throughout the Nation. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $1,-

500,000 for the fiscal year ending June 30, 1967, $2,500,000 for the fiscal year ending June 30, 1968, $5,000,000 for the fiscal year ending June 30, 1969, $7,500,000 for the fiscal year ending June 30, 1970, $8,000,000 for the fiscal year ending June 30, 1971, $10,000,000 for the fiscal year ending June 30, 1972, and $12,000,000 for the fiscal year ending June 30, 1973.

Grants for comprehensive public health services; authorization of appropriations; State plans; allotments; payments to States; Federal share; allocation of funds

(d) (1) There are authorized to be appropriated $70,000,000 for the fiscal year ending June 30, 1968, $90,000,000 for the fiscal year ending June 30, 1969, $100,000,000 for the fiscal year ending June 30, 1970, $130,000,000 for the fiscal year ending June 30, 1971, $145,000,000 for the fiscal year ending June 30, 1972, and $165,000,000 for the fiscal year ending June 30, 1973, to enable the Secretary to make grants to State health or mental health authorities to assist the States in establishing and maintaining adequate public health services, including the training of personnel for State and local health work. The sums so appropriated shall be used for making payments to States which have submitted, and had approved by the Secretary, State plans for provision of public health services, except that, for any fiscal year ending after June 30, 1968, such portion of such sums as the Secretary may determine, but not exceeding 1 per centum thereof, shall be available to the Secretary for evaluation (directly or by grants or contracts) of the program authorized by this subsection and the amount available for allotments hereunder shall be reduced accordingly.

(2) In order to be approved under this subsection, a State plan for provision of public health services must—

(A) provide for administration or supervision of administration by the State health authority or, with respect to mental health services, the State mental health authority;

(B) set forth the policies and procedures to be followed in the expenditure of the funds paid under this subsection;

(C) contain or be supported by assurances satisfactory to the Secretary that (i) the funds paid to the State under this subsection will be used to make a significant contribution toward providing and strengthening public health services in the various political subdivisions in order to improve the health of the people; (ii) such funds will be made available to other public or nonprofit private agencies, institutions, and organizations, in accordance with criteria which the Secretary determines are designed to secure maximum participation of local, regional, or metropolitan agencies and groups in the provision of such services; (iii) such funds will be used to supplement and, to the extent practical, to increase the level of funds that would otherwise be made available for the purposes for which the Federal funds are provided and not to supplant such non-Federal funds; and (iv) the plan is compatible with the total health program of the State;

(D) provide for the furnishing of public health services under the State plan in accordance with such plans as have been developed pursuant to subsection (a) of this section;

(E) provide that public health services furnished under the plan will be in accordance with standards prescribed by regulations, including standards as to the scope and quality of such services;

(F) provide such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods) as are found by the Secretary to be necessary for the proper and efficient operation of the plan;

(G) provide that the State health authority or, with respect to mental health services, the State mental health authority will from time to time, but not less often than annually, review and evaluate its State plan approved under this subsection and submit to the Secretary appropriate modifications thereof;

(H) provide that the State health authority or, with respect to mental health services, the State mental health authority, will make such reports, in such form and containing such information, as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of such reports;

(I) provide for such fiscal control and fund accounting procedures as may be necessary to assure the proper disbursement of and accounting for funds paid to the State under this subsection;

(J) contain such additional information and assurances as the Secretary may find necessary to carry out the purposes of this subsection;

(K) provide for services for the prevention and treatment of drug abuse and drug dependence, commensurate with the extent of the problem; and

(L) provide for services for the prevention and treatment of alcohol abuse and alcoholism, commensurate with the extent of the problem.

(3) From the sums appropriated to carry out the provisions of this subsection the several States shall be entitled for each fiscal year to allotments determined, in accordance with regulations, on the basis of the population and financial need of the respective States, except that no State's allotment shall be less for any year than the total amounts allotted to such State under formula grants for cancer control, plus other allotments under this section, for the fiscal year ending June 30, 1967.

(4) (A) From each State's allotment under this subsection for a fiscal year, the State shall be paid the Federal share of the expenditures incurred during such year under its State plan approved under this subsection. Such payments shall be made from time to time in advance on the basis of estimates by the Secretary of the sums the State will expend under the State plan, except that such adjustments as may be necessary shall be made on account of previously made underpayments or overpayments under this subsection.

(B) For the purpose of determining the Federal share for any State, expenditures by nonprofit private agencies, organizations, and groups shall, subject to such limitations and conditions as may be prescribed by regulations, be regarded as expenditures by such State or a political subdivision thereof.

(5) The "Federal share" for any State for purposes of this subsection shall be 100 per centum less than percentage which bears the same ratio to 50 per centum as the per capita income of such State bears to the per capital income of the United States; except that in no case shall such percentage be less than 33⅓ per centum or more than 66⅔ per centum, and except that the Federal share for the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Virgin Islands shall be 66⅔ per centum.

(6) The Federal shares shall be determined by the Secretary between July 1 and September 1 of each year. on the basis of the average per capita incomes of each of the States and of the United States for the most recent year for which satisfactory data are available from the Department of Commerce, and such determination shall be conclusive for the fiscal year beginning on

next July 1. The populations of the several States shall be determined on the basis of the latest figures for the population of the several States available from the Department of Commerce.

(7) At least 15 per centum of a State's allotment under this subsection shall be available only to the State mental health authority for the provision under the State plan of mental health services. Effective with respect to allotments under this subsection for fiscal years ending after June 30, 1968, at least 70 per centum of such amount reserved for mental health services and at least 70 per centum of the remainder of a State's allotment under this subsection shall be available only for the provision under the State plan of services in communities of the State.

Project grants for health services and related training; authorization of appropriations; review of application by appropriate areawide health planning agency

(e) There are authorized to be appropriated $90,000,000 for the fiscal year ending June 30, 1968, $95,000,000 for the fiscal year ending June 30, 1969, $80,000,000 for the fiscal year ending June 30, 1970, $109,500,000 for the fiscal year ending June 30, 1971, $135,000,000 for the fiscal year ending June 30, 1972, and $157,000,000 for the fiscal year ending June 30, 1973, for grants to any public or nonprofit private agency, institution, or organization to cover part of the cost (including equity requirements and amortization of loans on facilities acquired from the Office of Economic Opportunity or construction in connection with any program or project transferred from the Office of Economic Opportunity) of (1) providing services (including related training) to meet health needs of limited geographic scope or of specialized regional or national significance, or (2) developing and supporting for an initial period new programs of health services (including related training). Any grant made under this subsection may be made only if the application for such grant has been referred for review and comment to the appropriate areawide health planning agency or agencies (or, if there is no such agency in the area, then to such other public or nonprofit private agency or organization (if any) which performs similar functions) and only if the services assisted under such grant will be provided in accordance with such plans as have been developed pursuant to subsection (a) of this section.

Repeal

Subsec. (f) of this section repealed (less applicability to commissioned officers of the Public Health Service) by

Pub.L. 91–648, Title IV, §§ 403, 404, Jan. 5, 1971, 84 Stat. 1925, effective sixty days after Jan. 5, 1971.

Interchange of personnel with States

(f) (1) For the purposes of this subsection, the term "State" means a State or a political subdivision of a State, or any agency of either of the foregoing engaged in any activities related to health or designated or established pursuant to subparagraph (A) of paragraph (2) of subsection (a) of this section; the term "Secretary" means (except when used in paragraph (3) (D) the Secretary of Health, Education, and Welfare; and the term "Department" means the Department of Health, Education, and Welfare.

(2) The Secretary is authorized, through agreements or otherwise, to arrange for assignment of officers and employees of States to the Department and assignment to States of officers and employees in the Department engaged in work related to health, for work which the Secretary determines will aid the Department in more effective discharge of its responsibilities in the field of health as authorized by law, including cooperation with States and the provision of technical or other assistance. The period of assignment of any officer or employee under an arrangement shall not exceed two years.

(3) (A) Officers and employees in the Department assigned to any State pursuant to this subsection shall be considered, during such assignment, to be (i) on detail to a regular work assignment in the Department, or (ii) on leave without pay from their positions in the Department.

(B) Persons considered to be so detailed shall remain as officers or employees, as the case may be, in the Department for all purposes, except that the supervision of their duties during the period of detail may be governed by agreement between the Department and the State involved.

(C) In the case of persons so assigned and on leave without pay—

(i) if the rate of compensation (including allowances) for their employment by the State is less than the rate of compensation (including allowances) they would be receiving had they continued in their regular assignment in the Department, they may receive supplemental salary payments from the Department in the amount considered by the Secretary to be justified, but not at a rate in excess of the difference between the State rate and the Department rate; and

(ii) they may be granted annual leave and sick leave to the extent authorized by law, but only in circumstances considered by the Secretary to justify approval of such leave. Such officers and employees on leave without pay shall, notwithstanding any other provision of law, be entitled—

(iii) to continuation of their insurance under the Federal Employees' Group Life Insurance Act of 1954, and coverage under the Federal Employees Health Benefits Act of 1959, so long as the Department continues to collect the employee's contribution from the officer or employee involved and to transmit for timely deposit into the funds created under such Acts the amount of the employee's contributions and the Government's contribution from appropriations of the Department; and

(iv) (I) in the case of commissioned officers of the Service, to have their service during their assignment treated as provided in section 215(d) of this title for such officers on leave without pay, or (II) in the case of other officers and employees in the Department, to credit the period of their assignment under the arrangement under this subsection toward periodic or longevity step increases and for retention and leave accrual purposes, and, upon payment into the civil service retirement and disability fund of the percentage of their State salary, and of their supplemental salary payments, if any, which would have been deducted from a like Federal salary for the period of such assignment and payment by the Secretary into such fund of the amount which would have been payable by him during the period of such assignment with respect to a like Federal salary, to treat (notwithstanding the provisions of the Independent Offices Appropriation Act, 1959, under the head "Civil Service Retirement and Disability Fund") their service during such period, as service within the meaning of the Civil Service Retirement Act;

except that no officer or employee or his beneficiary may receive any benefits under the Civil Service Retirement Act, the Federal Employees Health Benefits Act of 1959, or the Federal Employees' Group Life Insurance Act of 1954, based on service during an assignment hereunder for which the officer or employee or (if he dies without making such election) his beneficiary elects to receive benefits, under any State retirement or insurance law or program, which the Civil Service Commission determines to be similar. The Department shall deposit currently in the funds created under the Federal Employees' Group Life Insurance Act of 1954, the Federal Employees Health Benefits Act of 1959, and the civil service retirement and disability fund, respectively, the amount of the Government's contribution under these Acts on account of service with respect to which employee contributions are collected as provided in subparagraph (iii) and the amount of the Government's contribution under the Civil Service Retirement Act on account of service with respect to which payments (of the amount which would have been deducted under that Act) referred to in subparagraph (iv) are made to such civil service retirement and disability fund.

(D) Any such officer or employee on leave without pay (other than a commissioned officer of the Service) who suffers disability or death as a result of personal injury sustained while in the performance of his duty during an assignment hereunder, shall be treated, for the purposes of the Federal Employees' Compensation Act, as though he were an employee, as defined in such Act, who had sustained such injury in the performance of duty. When such person (or his dependents, in case of death) entitled by reason of injury or death to benefits under that Act is also entitled to benefits from a State for the same injury or death, he (or his dependents in case of death) shall elect which benefits he will receive. Such election shall be made within one year after the injury or death, or such further time as the Secretary of Labor may for good cause allow, and when made shall be irrevocable unless otherwise provided by law.

(4) Assignment of any officer or employee in the Department to a State under this subsection may be made with or without reimbursement by the State for the compensation (or supplementary compensation), travel and transportation expenses (to or from the place of assignment), and allowances, or any part thereof, of such officer or employee during the period of assignment, and any such reimbursement shall be credited to the appropriation utilized for paying such compensation, travel or transportation expenses, or allowances.

(5) Appropriations to the Department shall be available, in accordance with the standardized Government travel regulations or, with respect to commissioned officers of the Service, the joint travel regulations, for the expenses of travel of officers and employees assigned to States under an arrangement under this subsection on either a detail or leave-without-pay basis and, in accordance with applicable law, orders, and regulations, for expenses of transportation of their immediate families and expenses of transportation of their household goods and personal effects, in connection with the travel of such officers and em-

ployees to the location of their posts of assignment and their return to their official stations.

(6) Officers and employees of States who are assigned to the Department under an arrangement under this subsection may (A) be given appointments in the Department covering the periods of such assignments, or (B) be considered to be on detail to the Department. Appointments of persons so assigned may be made without regard to the civil service laws. Persons so appointed in the Department shall be paid at rates of compensation determined in accordance with the Classification Act of 1949, and shall not be considered to be officers or employees of the Department for the purposes of (A) the Civil Service Retirement Act, (B) the Federal Employees' Group Life Insurance Act of 1954, or (C) unless their appointments result in the loss of coverage in a group health benefits plan whose premium has been paid in whole or in part by a State contribution, the Federal Employees Health Benefits Act of 1959. State officers and employees who are assigned to the Department without appointment shall not be considered to be officers or employees of the Department, except as provided in subsection (7), nor shall they be paid a salary or wage by the Department during the period of their assignment. The supervision of the duties of such persons during the assignment may be governed by agreement between the Secretary and the State involved.

(7) (A) Any State officer or employee who is assigned to the Department without appointment shall nevertheless be subject to the provisions of sections 203, 205, 207, 208, and 209 of Title 18.

(B) Any State officer or employee who is given an appointment while assigned to the Department, or who is assigned to the Department without appointment, under an arrangement under this subsection, and who suffers disability or death as a result of personal injury sustained while in the performance of his duty during such assignment shall be treated, for the purpose of the Federal Employees' Compensation Act, as though he were an employee, as defined in such Act, who had sustained such injury in the performance of duty. When such person (or his dependents, in case of death) entitled by reason of injury or death to benefits under that Act is also entitled to benefits from a State for the same injury or death, he (or his dependents, in case of death) shall elect which benefits he will receive. Such election shall be made within one year after the injury or death, or such further time as the Secretary of Labor may for good cause allow, and when made shall be irrevocable unless otherwise provided by law.

(8) The appropriations to the Department shall be available, in

accordance with the standardized Government travel regulations, during the period of assignment and in the case of travel to and from their places of assignmnt or appointment, for the payment of expenses of travel of persons assigned to, or given appointments by, the Department under an arragement under this subsection.

(9) All arrangements under this subsection for assignment of officers or employees in the Department to States or for assignment of officers or employees of States to the Department shall be made in accordance with regulations of the Secretary.

Consultation with State authorities; failure to comply with statute or rules and regulations; definitions

(g) (1) All regulations and amendments thereto with respect to grants to States under subsection (a) of this section shall be made after consultation with a conference of the State health planning agencies designated or established pursuant to subparagraph (A) of paragraph (2) of subsection (a) of this section. All regulations and amendments thereto with respect to grants to States under subsection (d) of this section shall be made after consultation with a conference of State health authorities and, in the case of regulations and amendments which relate to or in any way affect grants for services or other activities in the field of mental health, the State mental health authorities. Insofar as practicable, the Secretary shall obtain the agreement, prior to the issuance of such regulations or amendments, of the State authorities or agencies with whom such consultation is required.

(2) The Secretary, at the request of any recipient of a grant under this section, may reduce the payments to such recipient by the fair market value of any equipment or supplies furnished to such recipient and by the amount of the pay, allowances, traveling expenses, and any other costs in connection with the detail of an officer or employee to the recipient when such furnishing or such detail, as the case may be, is for the convenience of and at the request of such recipient and for the purpose of carrying out the State plan or the project with respect to which the grant under this section is made. The amount by which such payments are so reduced shall be available for payment of such costs (including the costs of such equipment and supplies) by the Secretary, but shall, for purposes of determining the Federal share under subsection (a) or (d) of this section, be deemed to have been paid to the State.

(3) Whenever the Secretary, after reasonable notice and opportunity for hearing to the health authority or, where appro-

priate, the mental health authority of a State or a State health planning agency designated or established pursuant to subparagraph (A) of paragraph (2) of subsection (a) of this section, finds that, with respect to money paid to the State out of appropriations under subsection (a) or (d) of this section, there is a failure to comply substantially with either—

(A) the applicable provisions of this section;

(B) the State plan submitted under such subsection; or

(C) applicable regulations under this section;

the Secretary shall notify such State health authority, mental health authority, or health planning agency, as the case may be, that further payments will not be made to the State from appropriations under such subsection (or in his discretion that further payments will not be made to the State from such appropriations for activities in which there is such failure), until he is satisfied that there will no longer be such failure. Until he is so satisfied, the Secretary shall make no payment to such State from appropriations under such subsection, or shall limit payment to activities in which there is no such failure.

(4) For the purposes of this section—

(A) The term "nonprofit" as applied to any private agency, institution, or organization means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual; and

(B) The term "State" includes the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia and the term "United States" means the fifty States and the District of Columbia.

July 1, 1944, c. 373, Title III, § 314, 58 Stat. 693; July 3, 1946, c. 538, § 9, 60 Stat, 424; June 16, 1948, c. 481, § 5, 62 Stat. 468; 1953 Reorg. Plan No. 1, § § 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 1, 1956, c. 852, § 18, 70 Stat. 910; July 22, 1958, Pub.L. 85–544, § 1, 72 Stat. 400; Oct. 5, 1961, Pub.L. 87–395, § 2(a)–(d), 75 Stat. 824; Sept. 25, 1962, Pub.L. 87–688, § 4(a) (1), 76 Stat. 587; Aug. 5, 1965, Pub.L. 89–109, § 4, 79 Stat. 436; Nov. 3, 1966, Pub.L. 89–749, § 3, 80 Stat. 1181; Dec. 5, 1967, Pub.L. 90–174, § § 2(a)–(f), 3(b) (2), 8(a), (b), 12(d), 81 Stat. 533–535, 540, 541; June 30, 1970, Pub.L. 91–296, Title I, § 111(b), Title IV, 401(b) (1) (C), (D), 84 Stat. 340, 352; Oct. 27, 1970, Pub.L. 91–513, Title I, § 3(b), 84 Stat. 1241; Oct. 30, 1970, Pub.L. 91–515, Title II, § § 220, 230, 240, 250, 260(a), (b), (c)

(1), 282, 84 Stat. 1304–1306, 1308; and amended Dec. 31, 1970, Pub.L. 91–616, Title III, § 331, 84 Stat. 1853.

Part G.—Quarantine and Inspection

§ 264. Regulations to control communicable diseases; apprehension, detention, and release of certain persons from particular places

(a) The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases for foreign countries into the States, or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General.

(c) Except as provided in subsection (d) of this section, regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d) On recommendation of the National Advisory Health Council, regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a communicable stage and (1) to be moving or about to move from a State to another State; or (2) to be a probable source of infection to individuals who, while infected with such disease in a communicable stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary.

July 1, 1944, c. 373, Title III, § 361, 58 Stat. 703; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 12, 1960, Pub.L. 86–624, § 29 (c), 74 Stat. 419.

1.5 ENVIRONMENTAL QUALITY BRANCH OF THE PLANT PROTECTION DIVISION

1.5a THE ORGANIC ACT OF 1862, AS AMENDED

7 U.S.C. §§2201–2212 (1967)

§ 2201. Establishment of Department

There shall be at the seat of government a Department of Agriculture, the general design and duties of which shall be to acquire and to diffuse among the people of the United States useful information on subjects connected with agriculture, in the most general and comprehensive sense of the word, and to procure, propagate, and distribute among the people new and valuable seeds and plants.

R.S. § 520.

§ 2202. Executive Department; Secretary

The Department of Agriculture shall be an executive department, under the supervision and control of a Secretary of Agriculture, who shall be appointed by the President, by and with the advice and consent of the Senate. The provisions of title IV of the Revised Statutes, including all amendments thereto, shall be applicable to said department; and all laws and parts of laws relating to the Department of Agriculture in existence February 9, 1889, as far as the same are applicable and not in conflict with said sections, and only so far, are continued in full force and effect.

Feb. 9, 1889, c. 122, §§ 1, 4, 25 Stat. 659.

§ 2203. Seal

The Secretary of Agriculture is authorized and directed to procure a proper seal, with such suitable inscriptions and devices as he may approve, to be known as the official seal of the Department of Agriculture, and to be kept and used to verify official documents, under such rules and regulations as he may prescribe.

Aug. 8, 1894, c. 238, 28 Stat. 272.

§ 2204. General duties of Secretary

The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain by means of books and correspondence, and by practical and scientific experiments, accurate records of which experiments shall be kept in his office, by the collection of statistics, and by any other appropriate means within his power; he shall collect new and valuable seeds and plants; shall test, by cultivation, the value of such of them as may require such tests; shall propagate such as may be worthy of propagation; and shall distribute them among agriculturists.

R.S. § 526.

§ 2205. Duties of former Commissioner of Agriculture transferred to Secretary

The Secretary of Agriculture is authorized and directed to perform all the duties named in all Acts of Congress in force on February 8, 1889, to be performed by the Commissioner of Agriculture.

Mar. 2, 1889, c. 373, 25 Stat. 840; July 14, 1890, c. 707, 26 Stat. 288.

§ 2206. Custody of property and records

The Secretary of Agriculture shall have charge, in the building and premises appropriated to the department, of the library, furniture, fixtures, records, and other property appertaining to it, or acquired for use in its business.

R.S. § 525.

§ 2207. Reports

The Secretary of Agriculture shall annually make a general report in writing of his acts to the President, in which he may recommend the publication of papers forming parts of or accompanying his report. He shall also make special reports on particular subjects whenever required to do so by the President or either House of Congress, or when he shall think the subject in his charge requires it.

R.S. §§ 528, 529; May 29, 1928, c. 901, § 1, 45 Stat. 993; Aug. 30, 1954, c. 1076, § 1 (6), 68 Stat. 966.

§ 2208. Same; expenditure of appropriations; accounting

The Secretary of Agriculture shall direct and superintend the expenditure of all money appropriated to the Department and render accounts thereof.

R.S. § 3677; Feb. 9, 1889, c. 122, §§ 1, 4, 25 Stat. 659.

§ 2209. Same; additional statement of expenditures

The Secretary of Agriculture shall furnish proper vouchers and accounts for the sums appropriated for the Department of Agriculture to the General Accounting Office.

Mar. 3, 1885, c. 338, § 2, 23 Stat. 356; Aug. 11, 1916, c. 313, 39 Stat. 492; June 10, 1921, c. 18, § 301, 42 Stat. 23; May 29, 1928, c. 901, § 1, 45 Stat. 992.

§ 2210. Under Secretary of Agriculture; appointment

There is established in the Department of Agriculture the position of Under Secretary of Agriculture, to be appointed by the President, by and with the advice and consent of the Senate.

Mar. 26, 1934, c. 89, Title I, 48 Stat. 467; Oct. 15, 1949, c. 695, § 3, 63 Stat. 880; July 31, 1956, c. 804, Title I, § 104(a), 70 Stat. 736.

§ 2211. Same; duties

The Under Secretary of Agriculture is authorized to exercise the functions and perform the duties of the first assistant of the Secretary of Agriculture within the meaning of section 3345 of Title 5 and shall perform such other duties as may be required by law or prescribed by the Secretary of Agriculture.
June 5, 1939, c. 181, 53 Stat. 809.

§ 2212. Assistant Secretary

There shall be in the Department of Agriculture an Assistant Secretary of Agriculture, to be appointed by the President, by and with the advice and consent of the Senate, who shall perform such duties as may be required by law or prescribed by the Secretary. The Assistant Secretary of Agriculture is authorized to perform such duties in the conduct of the business of the Department of Agriculture as may be assigned by the Secretary of Agriculture.
Feb. 9, 1889, c. 122, § 2, 25 Stat. 659; June 30, 1906, c. 3913, 34 Stat. 670.

1.5b THE PRESIDENT'S SCIENCE ADVISORY COMMITTEE REPORT ON PESTICIDES, MAY 14, 1963, p. 22

THE WHITE HOUSE

This report on the use of pesticides has been prepared for me by my Science Advisory Committee.

I have already requested the responsible agencies to implement the recommendations in the report, including the preparation of legislative and technical proposals which I shall submit to the Congress.

Because of its general public interest, I am releasing the report for publication.

JOHN F. KENNEDY.

THE WHITE HOUSE,
May 14, 1963.

* * * * * * *

C. Research needs

1. In order to develop safer, more specific controls of pests, it is recommended that government sponsored programs continue to shift their emphasis from research on broad spectrum chemicals to provide more support for research on:

[p. 20]

a. Selectively toxic chemicals
b. Non-persistent chemicals
c. Selective methods of application

d. Non-chemical control methods such as the use of attractants and the prevention of reproduction.

In the past few years, the Department of Agriculture has shifted its programs toward these specific controls. The Panel believes this trend should be continued and strengthened. Production of safer, more specific and less persistent pesticide chemicals is not an unreasonable goal; but its attainment will require extending research efforts beyond empirical approaches to more fundamental studies of subjects such as: The mode of action of pesticides; comparative toxicology; the metabolism of compounds in insects, plants, and higher animals; and the processes of chemical degradation and inactivation in nature. Such studies will also provide the information necessary to control those pests which are rapidly becoming resistant to currently available chemicals. Intensified effort is neeeded in the search for selective methods of pesticide application. Compounds are often applied in excessive quantity or frequency because of such inefficiencies as drift, uneven coverage, or distribution methods insufficiently specific to reach the target pest.

2. Toxicity studies related to man.

The toxicity data upon which registrations and tolerances are based should be more complete and of higher quality. Although data are available on acute toxic effects in man, chronic effects are more readily demonstrated in animals because their generation time is shorter, and thus the natural history of pesticide effects is telescoped chronologically. However, there will continue to be uncertainties in the extrapolation from experimental animals to man, and in the prediction of the nature and frequency of effects in humans on the basis of those observed in other forms of life.

The Panel recommends that toxicity studies include determination of:

a. Effects on reproduction through at least two generations in at least two species of warm-blooded animals. Observations should include effects on fertility, size and weight of litter, fetal mortality, teratogenicity, growth and development of sucklings and weanings.

b. Chronic effects on organs of both immature and adult animals, with particular emphasis on tumorigenicity and other effects common to the class of compounds of which the test substance is a member.

c. Possible synergism and potentiation of effects of commonly used pesticides with such commonly used drugs as sedatives, tranquilizers, analgesics, antihypertensive agents and steroid hormones, which are administered over prolonged periods.

[p. 21]

3. Toxicity Studies Related to Wildlife

The Panel recommends expanded research and evaluation by the Department of the Interior of the toxic effects of pesticides on wild vertebrates and invertebrates.

The study of wildlife presents a unique opportunity to discover the effects on the food chain of which each animal is a part, and to determine possible pathways through which accumulated and, in some cases, magnified pesticide residues can find their way directly or indirectly to wildlife and to man.

4. Amplification of Research Resources

Only by stimulating training and basic investigation in the fields of toxicology and ecology are research needs likely to be met. An increased output of basic research data and a continuing supply of capable research personnel could be ensured by a system of grants and contracts. Training grants, basic research grants, and contracts to universities and other nongovernmental research agencies funded by the Departments of Agriculture, Interior, and Health, Education and Welfare would stimulate this research. In order to accelerate immediate progress, it might prove useful to explore the contributions which can be made by competent research people and their facilities in other countries.

D. In order to strengthen public laws on pesticides, it is recommended that amendments to public laws be requested. These should:

1. Eliminate "Protest" registrations.

The Panel concurs with the Department of Agriculture that these technically evade the intent of the public laws. Industry needs an appeal mechanism, however, to protect it from arbitrary decisions. Public hearings could be held on such appeals.

2. Require that every pesticide formulation carry its official registration number on the label.

The Department of Agriculture has recommended such an amendment as a means of increasing the protection of the consumer.

3. Clarify the intent of the Federal Insecticide, Fungicide, and Rodenticide Act to protect fish and wildlife by including them as useful vertebrates and invertebrates.

4. Provide, as a part of the operating budgets of Federal control and eradication programs, funds to evaluate the efficiency of the programs and their effects on nontarget organisms in the environment. Results of these studies should be published promptly.

Approximately 20 million dollars were allocated to pest control programs in 1962, but no funds were provided for concurrent field studies of effects on the environment. The Department of Agriculture has repeatedly suggested that other interested agencies participate in the control programs, but funds have not been available except by diversion from other essential agency functions. [p. 22]

1.5c AGRICULTURAL RESEARCH SERVICE, DEPARTMENT OF AGRICULTURE AND RELATED AGENCIES APPROPRIATION ACT OF 1965

September 2, 1965, P.L. 88–573, Title I, 78 Stat. 862

DEPARTMENT OF AGRICULTURE AND RELATED AGENCIES APPROPRIATION ACT, 1965

PUBLIC LAW 88–573; 78 STAT. 862

[H.R. 11202]

AN ACT making appropriations for the Department of Agriculture and related agencies for the fiscal year ending June 30, 1965, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That:

The following sums are appropriated, out of any money in the Treasury not otherwise appropriated, for the Department of Agriculture and related agencies for the fiscal year ending June 30, 1965, and for other purposes: namely:

DEPARTMENT OF AGRICULTURE

TITLE I—GENERAL ACTIVITIES

AGRICULTURAL RESEARCH SERVICE

Salaries and Expenses

For expenses necessary to perform agricultural research relating to production, utilization, marketing, nutrition and consumer use, to control and eradicate pests and plant and animal diseases, and to perform related inspection, quarantine and regulatory work, and meat inspection: *Provided,* That appropriations hereunder shall be available for field employment pursuant to the second sentence of section 706(a) of the Organic Act of 1944 (5 U.S.C. 574), and not to exceed $75,000 shall be available for employment under section 15 of the Act of August 2, 1946 (5 U.S.C. 55a): *Provided further,* That appropriations hereunder shall be available for the operation and maintenance of aircraft and the purchase of not to exceed two for replacement only: *Provided further,* That appropriations hereunder shall be available pursuant to title 5, United States Code, section 565a, for the construction, alteration, and repair of buildings and improvements, but unless otherwise provided, the cost of constructing any one building (except headhouses connecting greenhouses) shall not exceed $20,000, except for six buildings to be constructed or improved at a cost not to exceed $45,000 each, and the cost of altering any one building during the fiscal year shall not exceed $7,500 or 7.5 per centum of the cost of the building, whichever is greater: *Provided further,* That the limitations on alterations contained in this Act shall not apply to a total of $100,000 for facilities at Beltsville, Maryland:

Research: For research and demonstrations on the production and utilization of agricultural products; agricultural marketing and distribution, not otherwise provided for; home economics or nutrition and consumer use of agricultural and associated products; and related research and services; and for acquisition of land by donation, exchange, or purchase at a nominal cost not to exceed $100, $114,991,000, plus not to exceed the following amounts, to remain available until expended, for the planning, construction, alteration, and equipping of research facilities; $1,000,000 for crops research facilities at Fort Collins, Colorado; $850,000 for facilities at the Agricultural Research Center, Beltsville, Maryland; $800,000 for a stored-products insects laboratory, Savannah, Georgia; $260,000 for plans for a livestock insects and toxicology laboratory, College Station, Texas; $338,000 for plans for a plant disease, nematode, and insect laboratory, Beltsville, Maryland; $160,000 for plans for an insect attractants and stored-product insects laboratory, Gainesville, Florida; $1,000,000 for a peanut quality research laboratory, at Dawson, Georgia, on a site acquired by donation; and $240,000 for plans for a Western cotton insects and physiology laboratory, Tempe, Arizona; a cotton disease labo- [p. 986] ratory, College Station, Texas; a cotton physiology laboratory, Stoneville, Mississippi; pilot cotton ginning facilities at Stoneville, Mississippi, and Mesilla Park, New Mexico; and facilities in the High Plains region in Texas for cotton ginning and storage research; in all, $119,639,000: *Provided,* That the limitations contained herein shall not apply to replacement of buildings needed to carry out the Act of April 24, 1948 (21 U.S.C. 113(a));

Plant and animal disease and pest control: For operations and measures, not otherwise provided for, to control and eradicate pests and plant and animal diseases and for carrying out assigned inspection, quarantine, and regulatory activities, as authorized by law, including expenses pursuant to the Act of February 28, 1947, as amended (21 U.S.C. 114b–c), $68,793,200, of which $1,500,000 shall be apportioned for use pursuant to section 3679 of the Revised Statutes, as amended, for the control of outbreaks of insects and plant diseases to the extent necessary to meet emergency conditions: *Provided*, That no funds shall be used to formulate or administer a brucellosis eradication program for the current fiscal year that does not require minimum matching by any State of at least 40 per centum: *Provided further*, That no funds in excess of $250,000 shall be available for carrying out the screwworm eradication program that does not require minimum matching by State or local sources of at least 50 per centum of the expenses of production, irradiation, and release of the screwworm flies: *Provided further*, That, in addition, in emergencies which threaten the livestock or poultry industries of the country, the Secretary may transfer from other appropriations or funds available to the agencies or corporations of the Department such sums as he may deem necessary, to be available only in such emergencies for the arrest and eradication of foot-and-mouth disease, rinderpest, contagious pleuropneumonia, or other contagious or infectious diseases of animals, or European fowl pest and similar diseases in poultry, and for expenses in accordance with the Act of February 28, 1947, as amended, and any unexpended balances of funds transferred under this head in the next preceding fiscal year shall be merged with such transferred amounts;

Meat inspection: For carrying out the provisions of laws relating to Federal inspection of meat, and meat-food products, and the applicable provisions of the laws relating to process or renovated butter, $30,837,000;

Special fund: To provide for additional labor to be employed under contracts and cooperative agreements to strengthen the work at research installations in the field, not more than $1,000,000 of the amount appropriated under this head for the previous fiscal year may be used by the Administrator of the Agricultural Research Service in departmental research programs in the current fiscal year, the amount so used to be transferred to and merged with the appropriation otherwise available under "Salaries and expenses, Research".

Salaries and Expenses (Special Foreign Currency Program)

For payments in foreign currencies which accrue under title I of the Agricultural Trade Development and Assistance Act of 1954, as amended (7 U.S.C. 1704), for market development research authorized by section 104(a) and for agricultural and forestry research and other functions related thereto authorized by section 104(k) of the Agricultural Trade Development and Assistance Act of 1954, as amended (7 U.S.C. 1704(a) (k)), to remain available until expended, $2,000,000: *Provided*, That this appropriation shall be available in addition to other appropriations for these purposes, for payments in the foregoing currencies: *Provided further*, That funds appropriated herein shall be used for payments in such foreign currencies as the Department determines are needed and can be used most effectively to carry out the purposes of this paragraph, and such foreign currencies shall, pursuant to the provisions of section 104(a), be set aside for sale to the Department before foreign currencies which accrue under said title I are made available for other United States uses: *Provided further*, That not to exceed $25,000 of this appropriation shall be available for payments in foreign currencies for

[p. 987]

1.6 SPECIAL PACKAGING OF HOUSEHOLD SUBSTANCES FOR PROTECTION OF CHILDREN

15 U.S.C. §1471 *et seq.* (1970)

Sec.
1471. Definitions.
1472. Special packaging standards.
  (a) Establishment.
  (b) Considerations.
  (c) Publication of findings, reasons, and citation of statutory authorizations.
  (d) Limitation.
1473. Conventional packages, marketing.
  (a) Noncomplying packages for elderly or handicapped persons; labeling statements.
  (b) Noncomplying packages for substances dispensed pursuant to orders of medical practitions.
  (c) Exclusive use of special packaging; necessary circumstances.
1474. Regulations for special packaging standards.
  (a) Rule making procedure; election and application of procedure under section 371 of Title 21; publication of election proposal.
  (b) Judicial review; petition; record; additional evidence; jurisdiction of court of appeals; scope of review; relief pending review; finality of judgment; review by Supreme Court.
1475. Technical advisory committee.
  (a) Appointment; designation of chairman; representation of interests; consultation of Secretary with committee.
  (b) Compensation and travel expenses.
1476. Federal preemption.

§ 1471. Definitions

For the purpose of this Act—

(1) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(2) The term "household substance" means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is—

(A) a hazardous substance as that term is defined in section 1261(f) of this title;

(B) a pesticide as that term is defined in section 135(a) of Title 7;

(C) a food, drug, or cosmetic as those terms are defined section 321 of Title 21; or

(D) a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.

(3) The term "package" means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, and, for purposes of section 1473(a) (2) of this title, also means any outer container or wrapping used in the retail display of any such substance to consumers. Such term does not include—

(A) any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or

(B) any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only such container or wrapping.

(4) The term "special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(5) The term "labeling" means all labels and other written, printed, or graphic matter (A) upon any household substance or its package, or (B) accompanying such substance.

Pub.L. 90–601, § 2, Dec. 30, 1970, 84 Stat. 1670.

§ 1472. Special packaging standards—Establishment

(a) The Secretary, after consultation with the technical advisory committee provided for in section 1475 of this title, may establish in accordance with the provisions of this Act, by regulation, standards for the special packaging of any household substance if he finds that—

(1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

Considerations

(b) In establishing a standard under this section, the Secretary shall consider—

(1) the reasonableness of such standard;

(2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) the manufacturing practices of industries affected by this Act; and

(4) the nature and use of the household substance.

Publication of findings, reasons, and citation of statutory authorizations

(c) In carrying out this Act, the Secretary shall publish his findings, his reasons therefor, and citation of the sections of statutes which authorize his action.

Limitation

(d) Nothing in this Act shall authorize the Secretary to prescribe specific packaging designs, product content, package quanity, or, with the exception of authority granted in section 1473(a)(2) of this title, labeling. In the case of a household substance for which special packaging is required pursuant to a regulation under this section, the Secretary may in such regulation prohibit the packaging of such substance in packages which he determines are unnecessarily attractive to children.

Pub.L. 91–601, § 3, Dec. 30, 1970, 84 Stat. 1670.

§ 1473. Conventional packages, marketing—Noncomplying packages for elderly or handicapped persons; labeling statements

(a) For the purpose of making any household substance which is subject to a standard established under section 1472 of this title readily available to elderly or handicapped persons unable to use such substance when packaged in compliance with such standard, the manufacturer or packer, as the case may be, may package any household substance, subject to such a standard, in packaging of a single size which does not comply with such standard if—

(1) the manufacturer (or packer) also supplies such substance in packages which comply with such standard; and

(2) the packages of such substance which do not meet such standard bear conspicuous labeling stating; "This package for households without young children"; except that the Secretary may be regulation prescribe a substitute statement to the same effect for packaging too small to accommodate such labeling.

Noncomplying packages for substances dispensed pursuant to orders of medical practitioners

(b) In the case of a household substance which is subject to such a standard and which is dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner authorized to perscribe, such substance may be dispensed in noncomplying packages only when directed in such order or when requested by the purchaser.

Exclusive use of special packaging; necessary circumstances

(c) In the case of a household substance subject to such a standard which is packaged under subsection (a) of this section in a noncomplying package, if the Secretary determines that such substance is not also being supplied by a manufacturer (or packer) in popular size packages which comply with such standard, he may, after giving the manufacturer (or packer) an opportunity to comply with the purposes of this Act, by order require such substance to be packaged by such manufacturer (or packer) exclusively in special packaging complying with such standard if he finds, after opportunity for hearing, that such exclusive use of special packaging is necessary to accomplish the purposes of this Act.

Pub.L. 91–601, § 4, Dec. 30, 1970, 84 Stat. 1671.

§ 1474. Regulations for special packaging standards—Rule making procedure; election and application of procedure under section 371 of Title 21; publication of election and proposal

(a) Proceedings to issue, amend, or repeal a regulation prescribing a standard under section 1472 of this title shall be conducted in accordance with the procedures prescribed by section 553 (other than paragraph (3)(B) of the last sentence of subsection (b) of such section) of Title 5 unless the Secretary elects the procedures prescribed by subsection (e) of section 371 of Title 21, in which event such subsection and subsections (f) and (g) of such section 371 shall apply to such proceedings. If the Secretary makes such election, he shall publish that fact with the proposal required to be published under paragraph (1) of such subsection (e).

Judicial review; petition; record; additional evidence; jurisdiction of court of appeals; scope of review; relief pending review; finality of judgment; review by Supreme Court

(b) (1) In the case of any standard prescribed by a regulation issued in accordance with section 553 of Title 5, any person who will be adversely affected by such a standard may, at any time prior to the 60th day after the regulation prescribing such standard is issued by the Secretary, file a petition with the United States Court of Appeals for the circuit in which such person resides or has his principal place of business for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his standard, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there was no opportunity to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary in a hearing or in such other manner, and upon such terms and conditions, as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original standard, with the return of such additional evidence.

(3) Upon the filing of the petition under paragraph (1) of this subsection the court shall have jurisdiction to review the standard of the Secretary in accordance with subparagraphs (A), (B), (C), and (D) of paragraph (2) of section 706 of Title 5. If the court ordered additional evidence to be taken under paragraph (2) of this subsection, the court shall also review the Secretary's standard to determine if, on the basis of the entire record before the court pursuant to paragraphs (1) and (2) of this subsection, it is supported by substantial evidence. If the court finds the standard is not so supported, the court may set it aside.

(4) With respect to any standard reviewed under this subsection, the court may grant appropriate relief pending conclusion of the review proceedings, as provided in section 705 of such Title 5.

(5) The judgment of the court affirming or setting aside, in whole or in part, any such standard of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of Title 28.

Pub.L. 91-601, § 5, Dec. 30, 1970, 84 Stat. 1671.

§ 1475. Technical advisory committee—Appointment; designation of chairman; representation of interests; consultation of Secretary with committee

(a) For the purpose of assisting in carrying out the purposes of this Act, the Secretary shall appoint a technical advisory committee, designating a member thereof to be chairman, composed of not more than eighteen members who are representative of (1) the Department of Health, Education, and Welfare, (2) the Department of Commerce, (3) manufacturers of household substances subject to this Act, (4) scientists with expertise related to this Act and licensed practitioners in the medical field, (5) consumers, and (6) manufacturers of packages and closures for household substances. The Secretary shall consult with the technical advisory committee in making findings and in establishing standards pursuant to this Act.

Compensation and travel expenses

(b) Members of the technical advisory committee who are not regular full-time employees of the United States shall, while attending meetings of such committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding $100 per diem, including traveltime, and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of Title 5 for persons in the Government service employed intermittently.

Pub.L. 91-601, § 6, Dec. 30, 1970, 84 Stat. 1672.

§ 1476. Federal preemption

Whenever a standard established by the Secretary under this Act applicable to a household substance is in effect no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the standard established under section 1472 of this title (and any exemption therefrom and requirement related thereto) of this Act.

Pub.L. 91-601, § 8, Dec. 30, 1970, 84 Stat. 1673.

1.6a POISON PREVENTION PACKAGING ACT OF 1970

December 30, 1970, P.L. 91-601, 84 Stat. 1670

AN ACT

To provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using or ingesting household substances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

SECTION 1. This Act may be cited as the "Poison Prevention Packaging Act of 1970".

SEC. 2. For the purpose of this Act—

(1) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(2) The term "household substance" means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is—

(A) a hazardous substance as that term is defined in section 2(f) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f));

(B) an economic poison as that term is defined in section 2a of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(a));

(C) a food, drug, or cosmetic as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(D) a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.

(3) The term "package" means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, and, for purposes of section 4(a)(2) of this Act, also means any outer container or wrapping used in the retail display of any such substance to consumers. Such term does not include—

(A) any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or

(B) any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only such container or wrapping.

(4) The term "special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(5) The term "labeling" means all labels and other written, printed, or graphic matter (A) upon any household substance or its package, or (B) accompanying such substance.

SEC. 3. (a) The Secretary, after consultation with the technical advisory committee provided for in section 6 of this Act, may establish in accordance with the provisions of this Act, by regulation, standards for the special packaging of any household substance if he finds that—

(1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children [p. 1670] from serious personal injury or illness resulting from handling, using, or ingesting such substance; and

(2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

(b) In establishing a standard under this section, the Secretary shall consider—

(1) the reasonableness of such standard;

(2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) the manufacturing practices of industries affected by this Act; and

(4) the nature and use of the household substance.

(c) In carrying out this Act, the Secretary shall publish his findings, his reasons therefor, and citation of the sections of statutes which authorize his action.

(d) Nothing in this Act shall authorize the Secretary to prescribe specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 4(a) (2) of this Act, labeling. In the case of a household substance for which special packaging is required pursuant to a regulation under this section, the Secretary may in such regulation prohibit the packaging of such substance in packages which he determines are unnecessarily attractive to children.

SEC. 4. (a) For the purpose of making any household substance which is subject to a standard established under section 3 readily available to elderly or handicapped persons unable to use such substance when packaged in compliance with such standard, the manufacturer or packer, as the case may be, may package any household substance, subject to such a standard, in packaging of a single size which does not comply with such standard if—

(1) the manufacturer (or packer) also supplies such substance in packages which comply with such standard; and

(2) the packages of such substance which do not meet such standard bear conspicuous labeling stating: "This package for households without young children"; except that the Secretary may by regulation prescribe a substitute statement to the same effect for packaging too small to accommodate such labeling.

(b) In the case of a household substance which is subject to such a standard and which is dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner authorized to prescribe, such substance may be dispensed in noncomplying packages only when directed in such order or when requested by the purchaser.

(c) In the case of a household substance subject to such a standard which is packaged under subsection (a) in a noncomplying package, if the Secretary determines that such substance is not also being supplied by a manufacturer (or packer) in popular size packages which comply with such standard, he may, after giving the manufacturer (or packer) an opportunity to comply with the purposes of this Act, by order require such substance to be packaged by such manufacturer (or packer) exclusively in special packaging complying with such standard if he finds, after opportunity for hearing, that such exclusive use of special packaging is necessary to accomplish the purposes of this Act.

SEC. 5. (a) Proceedings to issue, amend, or repeal a regulation prescribing a standard under section 3 shall be conducted in accordance with the procedures prescribed by section 553 (other than paragraph (3) (B) of the last sentence of subsection (b) of such section) of title 5 of the United States Code unless the [p. 1671] Secretary elects the procedures prescribed by subsection (e) of section 701 of the Federal Food, Drug and Cosmetic Act, in which event such subsection and subsections (f) and (g) of such section

701 shall apply to such proceedings. If the Secretary makes such election, he shall publish that fact with the proposal required to be published under paragraph (1) of such subsection (e).

(b) (1) In the case of any standard prescribed by a regulation issued in accordance with section 553 of title 5 of the United States Code, any person who will be adversely affected by such a standard may, at any time prior to the 60th day after the regulation prescribing such standard is issued by the Secretary, file a petition with the United States Court of Appeals for the circuit in which such person resides or has his principal place of business for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his standard, as provided in section 2112 of title 28 of the United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there was no opportunity to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary in a hearing or in such other manner, and upon such terms and conditions, as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original standard, with the return of such additional evidence.

(3) Upon the filing of the petition under paragraph (1) of this subsection the court shall have judisdiction to review the standard of the Secretary in accordance with subparagraphs (A), (B), (C), and (D) of paragraph (2) of section 706 of title 5 of the United States Code. If the court ordered additional evidence to be taken under paragraph (2) of this subsection, the court shall also review the Secretary's standard to determine if, on the basis of the entire record before the court pursuant to paragraphs (1) and (2) of this subsection, it is supported by substantial evidence. If the court finds the standard is not so supported, the court may set it aside.

(4) With respect to any standard reviewed under this subsection, the court may grant appropriate relief pending conclusion of the review proceedings, as provided in section 705 of such title 5.

(5) The judgment of the court affirming or setting aside, in whole or in part, any such standard of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28 of the United States Code.

SEC. 6. (a) For the purpose of assisting in carrying out the purposes of this Act, the Secretary shall appoint a technical advisory committee, designating a member thereof to be chairman, composed of not more than eighteen members who are representative of (1) the Department of Health, Education, and Welfare, (2) the Department of Commerce, (3) manufacturers of household substances subject to this Act, (4) scientists with expertise related to this Act and licensed practitioners in the medical field, (5) consumers, and (6) manufacturers of packages and closures for household substances. The Secretary shall consult with the technical advisory committee in making findings and in establishing standards pursuant to this Act.

[p. 1672]

(b) Members of the technical advisory committee who are not regular full-time employees of the United States shall, while attending meetings of such committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding $100 per diem, including traveltime, and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

SEC. 7. (a) Section 2(p) of the Federal Hazardous Substances Act (15 U.S.C. 1261(p)) is amended—

(1) by striking out "which substance" in the part preceding paragraph (1) and inserting in lieu thereof "if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if such substance"; and

(2) by adding the following after below paragraph (2):

"The term 'misbranded hazardous substance' also includes a household substance as defined in section 2(2)(D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in paragraph 1 of section 2(f) of this Act and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.".

(b) Section 2z(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(z) (2)) is amended by striking out the period at the end of paragraph (h) of such section and inserting in lieu thereof "; or" and by adding at the end thereof a new paragraph as follows:

> (i) if its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(c) Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end thereof a new paragraph as follows:

"(n) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(d) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end thereof a new paragraph as follows:

"(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(e) Section 503(b) (2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b) (2)) is amended by striking out "and (h)" and inserting in lieu thereof ", (h), and (p)".

(f) Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amended by adding at the end thereof a new paragraph as follows:

"(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

SEC. 8. Whenever a standard established by the Secretary under this Act applicable to a household substance is in effect, no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the standard established under section 3 (and any exemption therefrom and requirement related thereto) of this Act.

[p. 1673]

SEC. 9. This Act shall take effect on the date of its enactment. Each regulation establishing a special packaging standard shall specify the date such standard is to take effect which date shall not be sooner than one hundred and eighty days or later than one year from the date such regulation is final, unless the Secretary, for good cause found, determines that an earlier effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier date shall apply. No such standard shall be effective as to household substances subject to this Act packaged prior to the effective date of such final regulation.

Approved December 30, 1970.

[p. 1674]

1.6a (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 91-1642, 91st Cong., 2d Sess. (1970)

POISON PREVENTION PACKAGING ACT OF 1970

DECEMBER 1, 1970.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 2162]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (S. 2162) for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. This act may be cited as the "Poison Prevention Packaging Act of 1970."

SEC. 2. For the purpose of this Act—

(1) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(2) The term "household substance" means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is—

(A) a hazardous substance as that term is defined in section 2(f) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f));

(B) an economic poison as that term is defined in section 2a of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(a));

(C) a food, drug, or cosmetic as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(D) a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.

[p. 1]

(3) The term "package" means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, and, for purposes of section 4(a) (2) of this Act, also means any outer container or wrapping used in the retail display of any such substance to consumers. Such term does not include—

(A) any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or

(B) any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only such container or wrapping.

(4) The term "special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(5) The term "labeling" means all labels and other written, printed, or graphic matter (A) upon any household substance or its package, or (B) accompanying such substance.

SEC. 3. (a) The Secretary, after consultation with the technical advisory committee provided for in section 6 of this Act, may establish in accordance with the provisions of this Act, by regulation, standards for the special packaging of any household substance if he finds that—

(1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

(b) In establishing a standard under this section, the Secretary shall consider—

(1) the reasonableness of such standard;

(2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) the manufacturing practices of industries affected by this Act; and

(4) the nature and use of the household substance.

(c) In carrying out this Act, the Secretary shall publish his findings, his reasons therefor, and citation of the sections of statutes which authorize his action.

(d) Nothing in this Act shall authorize the Secretary to prescribe specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 4(a)(2) of this Act, labeling. In the case of a household substance for which special packaging is required under a regulation under this section, the Secretary may in such regulation prohibit the packaging of such substance in packages which he determines are unnecessarily attractive to children.

SEC. 4. (a) For the purpose of making a household substance for which a standard has been established pursuant to this Act readily available to elderly or handicapped persons who may be unable to use special packaging and to those households without young children, such household substance may be packaged in packages not complying with such standard if—

(1) such substance is supplied to the consumer in at least one popular size package which complies with such standard; and

(2) the packages which do not meet such standard bear, in conformity with regulations of the Secretary, conspicuous labeling stating: "This product is also available in special packaging which is recommended for use in households with young children".

In the case of a household substance dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner who is authorized to prescribe, such substance may be sold in noncomplying packaging only when directed in the order of such practitioner or when requested by the purchaser.

(b) Whenever the Secretary determines that any household substance packaged in noncomplying packages is not also being supplied by a manufacturer or packer in popular size packages which comply with the standard established for such substance, he may, after giving the manufacturer or packer an opportunity to comply with the purpose of this Act, by order require such substance to be packaged by such manufacturer or packer exclusively in special packaging complying with such standard if he finds, after opportunity for hearing, that such exclusive use of such packaging is necessary to accomplish the purposes of this Act.

[p. 2]

SEC. 5. (a) Proceedings to issue, amend, or repeal a regulation prescribing a standard under section 3 shall be conducted in accordance with the procedures prescribed by section 553 (other than clause (B) of the last sentence of subsection (b) of such section) of title 5 of the United States Code unless the Secretary elects the procedures prescribed by subsection (e) of section 701 of the Federal Food, Drug, and Cosmetic Act, in which event such subsection and subsections (f) and (g) of such section 701 shall apply to such proceedings. If the Secretary makes such election, he shall publish that fact with the proposal required to be published under paragraph (1) of such subsection (e).

(b) In the case of any standard prescribed by a regulation issued in accordance with section 553 of title 5 of the United States Code, any person who will be adversely affected by such a standard may, at any time prior to the 60th day after the regulation prescribing such standard is issued by the Secretary, file a petition with the United States Court of Appeals for the circuit in which such person resides or has his principal place of business for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his standard, as provided in section 2112 of title 28 of the United States Code.

(c) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there was no opportunity to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary in a hearing or in such other manner, and upon such terms and conditions, as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original standard, with the return of such additional evidence.

(d) Upon the filing of the petition under subsection (b) the court shall have jurisdiction to review the standard of the Secretary in accordance with subparagraphs (A), (B), (C), and (D) of paragraph (2) of section 706 of title 5 of the United States Code. If the court ordered additional evidence to be taken under subsection (c), the court shall also review the Secretary's standard to determine if, on the basis of the entire record before the court pursuant to subsections (b) and (c), it is supported by substantial evidence. If the court finds the standard is not so supported, the court may set it aside. With respect to any standard reviewed under this subsection, the court may grant appropriate relief pending conclusion of the review proceedings, as provided in section 705 of such title 5.

(e) The judgment of the court affirming or setting aside, in whole or in part, any such standard of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28 of the United States Code.

SEC. 6. (a) For the purpose of assisting in carrying out the purposes of this Act, the Secretary shall appoint a technical advisory committee, designating a member thereof to be chairman, composed of not more than eighteen members who are representative of (1) the Department of Health, Education, and Welfare, (2) the Department of Commerce, (3) manufacturers of household substances subject to this Act, (4) scientists with expertise related to this Act and licensed practitioners in the medical field, (5) consumers, and (6) manufacturers of packages and closures for household substances. The Secretary shall consult with the technical advisory committee in making findings and in establishing standards pursuant to this Act.

(b) Members of the technical advisory committee who are not regular full-time employees of the United States shall, while attending meetings of such committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding $100 per diem, including traveltime, and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

SEC. 7. (a) Section 2(p) of the Federal Hazardous Substances Act (15 U.S.C. 1261 (p)) is amended—

(1) by striking out "which substance" in the part preceding paragraph(1) and inserting in lieu thereof "if the packaging or labeling of such substance is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if such substance"; and

[p. 3]

(2) by adding the following after and below paragraph (2);

"The term 'misbranded hazardous substance' also includes a household substance as defined in section 2(2) (D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in paragraph 1 of section 2(f) of this Act and its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.".

(b) Section 2z(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(z)(2)) is amended by striking out the period at the end of paragraph (h) of such section and inserting in lieu thereof "; or" and by adding at the end thereof a new paragraph as follows:

"(i) if its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(c) Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end thereof a new paragraph as follows:

"(n) If its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(d) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end thereof a new paragraph as follows:

"(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(e) Section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(2)) is amended by striking out "and (h)" and inserting in lieu thereof ", (h), and (p)".

(f) Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amended by adding at the end thereof a new paragraph as follows:

"(f) If its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

SEC. 8. Whenever a standard established by the Secretary under this Act applicable to a household substance is in effect, no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exception therefrom and requirement related thereto) which is not identical to the standard established under section 3 (and any exemption therefrom and requirement related thereto) of this Act.

SEC. 9. This Act shall take effect on the date of its enactment. Each regulation establishing a special packaging standard shall specify the date such standard is to take effect which date shall not be sooner than one hundred

and eighty days or later than one year from the date such regulation is final, unless the Secretary, for good cause found, determines that an earlier effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier date shall apply. No such standard shall be effective as to household substances subject to this Act packaged prior to the effective date of such final regulation.

NEED FOR LEGISLATION

Statistics compiled by the national clearinghouse for poison control centers document the need for additional measures to curb accidental poisonings which largely involve small children. The national clearinghouse, operated by the Office of Product Safety in the Food and Drug Administration, determined from reports received from 420 poison control centers located across the Nation that over 105,000 ingestions of drugs and potentially toxic household products occurred in 1968. Children under 5 years of age were involved in 71,563 of these ingestion accidents, and 4,129 hospitalizations occurred within this age group as a result of these accidents. These data also showed that during 1968 the State of Illinois reported 12,503 such ingestions by children under 5 years of age. In California, the Los Angeles poison control center, which serves much of the southern portion of the State, reported 13,404 poisoning accidents involving this age group during 1968.

[p. 4]

The principal product categories involved in the 1968 national poisoning accident data were, in descending order of frequency, cleaning and polishing agents, cosmetics, pesticides, turpentine and related paint products, and plants. Statistics compiled by the national clearinghouse since it was established in 1957 have consistently shown that drugs and medicines account for about half of the total poisoning accidents involving small children. In this category, aspirin is the most frequently involved product.

In the household specialties area, some chemicals cause serious illness requiring lengthy hospitalization and produce injuries from which the child may never fully recover. Furniture polishes containing petroleum distillates are one of the frequently ingested products which present a serious hazard to small children. On ingestion, these petroleum distillates are readily aspirated into the lungs and may lead to severe chemical pneumonitis in a matter of minutes.

The Food and Drug Administration received reports in 1968 of 782 children under age 5 who accidentally ingested petroleum distillate furniture polish. Of this number, 178 were hospitalized. The previous year, 675 ingestions and 170 hospitalizations were attributed to these products. In 1966, there were 567 such ingestions, which resulted in 100 children being hospitalized. Eight deaths occurred in this age group from the ingestion of petroleum distillate type furniture polishes in both 1966 and 1967. Six such deaths have been recorded for 1968, although mortality data for that year was not complete at the time this figure was submitted.

During 1967, the last year for which complete mortality data are available, the National Center for Health Statistics of the Public Health Service recorded the death of 325 children from accidental poisoning. While the total of 325 child deaths from this cause may not appear large in proportion to the 105,000 ingestion incidents reported for this age group, it is a tragic and needless toll which dictates that every effort be employed to reduce and, if possible, eliminate it.

In hearings held by your committee and the Senate committee on this legislation and in agency reports to the committees, a number of products were mentioned as potentially hazardous to children if not appropriately packaged. Of course, mere reference to the hazards of a particular product will not necessarily mean that its packaging will be regulated under this legislation. Regulation under this legislation must be preceded by a finding that as a result of the degree or nature of the hazard to children in the availability of the product, by reason of its packaging, special packaging is required to prevent serious injury or illness and a finding that special packaging for the product is technically feasible, practicable, and appropriate.

MARKETING OF PRODUCTS IN CONVENTIONAL AND SPECIAL SAFETY PACKAGES

The only major controversy with respect to this legislation involves section 4 of the bill which sets forth the conditions under which products in conventional packages may be marketed. The controversial issue is whether special safety packages should become the rule or the exception on the shelves of supermarkets and other stores. Under the following conditions, the bill as [p. 5] reported by your committee would permit the marketing in conventional packages of household substances for which a special packaging standard was in effect:

First, prescription drugs dispensed pursuant to the order of a physician, dentist, or other licensed medical practitioner, who is authorized to prescribe, may be made available in conventional packaging only when such packaging is directed by such practitioner in such order or when it is requested by the purchaser.

Secondly, any other household substance for which a special packaging standard has been established may be made available in conventional packages if such substance is supplied to the consumer in special safety packages (complying with the standard) in at least one popular size. Furthermore, manufacturers would be required to label conventional packages with a conspicuous label stating: "This product is also available in special packaging which is recommended for use in households with young children".

[p. 6]

SECTION-BY-SECTION ANALYSIS

Section 1—Short title "Poison Prevention Packaging Act of 1970"

Section 2—Definitions

1. "Secretary" means Secretary of Health, Education, and Welfare.

2. "Household substance" means any substance customarily sold for use, or stored, in and around the household, which is—

(a) a hazardous substance subject to the Federal Hazardous Substance Act;

(b) an economic poison as defined in the Federal Insecticide, Fungicide, and Rodenticide Act;

(c) a food, drug, or cosmetic as defined in the Federal Food, Drug, and Cosmetic Act; or

(d) a substance intended for use as fuel when stored in a portable container and used in heating, cooking, or refrigeration.

3. "Package" means the immediate container or wrapping in which a household substance is kept, and, for labeling purposes, any outer container or wrapping used for retail display, but does not include shipping containers except those which are used for shipment or delivery to consumers and which are the only containers.

4. "Special packaging" means packaging designed to be significantly difficult for children under 5 years of age to open or obtain harmful amounts from the container within a reasonable time but not difficult for normal adults to use properly. (Special packaging does not mean packaging which all such children are unable to open or obtain a harmful amount within a reasonable time.)

5. "Labeling" means labels or printed matter upon any household substance or its package or accompanying such substance.

Section 3—Establishment of standards

(a) Authorizes the Secretary after consultation with the technical advisory committee, to establish, by regulation, standards for special packaging if he finds—

(1) the hazard of the substance to children, by reason of its packaging, is such that special packaging is required to protect children; and

(2) the packaging to be required by the standard is technically feasible, practicable, and appropriate.

(b) In establishing standards, the Secretary shall consider—

(1) the reasonableness of the standard;

(2) scientific and technical data concerning special packaging and the harmful effects caused by the substance;

(3) the manufacturing practices of affected industries; and

(4) the nature and use of the substance.

(c) The Secretary shall publish his findings, his reasons therefor, and cite appropriate provisions of the applicable statutes authorizing his actions in implementing the Act.

(d) The Secretary shall not specify package designs, product content, package quantity, and labeling except as provided in section 4; however, the Secretary may prohibit, by regulation, packaging unnecessarily attractive to children.

[p. 7]

Section 4—Marketing of conventional packages

(a) To make available conventional packages to the handicapped elderly or to households without children a substance may be packaged without compliance to the standards if—

(1) such product is available in at least one popular size of special packaging; and

(2) noncomplying packages are conspicuously labeled "This product is also available in special packaging which is recommended for use in households with young children."

Substances dispensed pursuant to prescription may be sold in noncomplying packages only when so directed by practitioner or requested by the purchaser.

(b) Whenever the Secretary finds that substances packaged in noncomplying packages by a manufacturer are not also being supplied in popular size packages which comply with the standard, he may, after providing an opportunity to comply, require the manufacturer to package exclusively in complying special packaging if he finds, after opportunity for hearing, such exclusive use of special packaging is necessary to accomplish the purposes of the Act.

Section 5—Procedural requirements

(a) Procedures to issue regulations establishing packaging standards shall be pursuant to the informal rulemaking provisions of chapter 5 of title 5 of the United States Code unless the Secretary elects the procedures under the Federal Food, Drug, and Cosmetic Act. If the Secretary so elects he shall publish that fact with the proposed standard.

(b) If proceedings are conducted pursuant to such informal rulemaking provisions, adversely affected persons may, within 60 days after issuance of the standards, petition an appropriate court of appeals for judicial review of the standard. A copy of the petition shall be transmitted to the Secretary by the clerk of the court and the Secretary shall file the record upon which he based the standard.

(c) If the petitioner shows that additional evidence is material and that there was no opportunity to adduce such evidence during the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary in a hearing or by other means the court deems proper. The Secretary may modify his findings, and modify or set aside the standard if indicated by the additional evidence.

(d) The court shall have jurisdiction to set aside a standard if it is not, on the basis of the entire record, supported by substantial evidence.

(e) The judgment of the court may be appealed to the Supreme Court.

Section 6—Advisory committee

(a) The Secretary shall establish a technical advisory committee of not more than 18 members who are representative of (1) Department of Health, Education, and Welfare, (2) Department of Commerce, (3) manufacturers of household substances, (4) scientists and medical practitioners, (5) consumers, and (6) manufacturers of packages or closures. The Secretary shall consult the committee in making findings and establishing standards.

[p. 8]

(b) Compensation of committee members not regular employees of the United States may be fixed by Secretary but not to exceed $100 per day (including travel time) and travel expenses and per diem authorized.

Section 7—Enforcement

(a) Amends the Federal Hazardous Substances Act to make substances which are subject to that Act misbranded if they are labeled or packaged in violation of section 3 or 4 of this Act.

(b) Amends the Federal Insecticide, Fungicide, and Rodenticide Act to make substances subject to that Act misbranded if the labeling or packaging is in violation of sections 3 or 4 of this Act.

(c) Amends section 403 of the Federal Food, Drug, and Cosmetic Act to make food misbranded if packaged or labeled in violation of sections 3 or 4 of this Act.

(d) Amends section 502 of the Federal Food, Drug, and Cosmetic Act to make drugs misbranded if they are packaged or labeled in violation of sections 3 or 4 of this Act.

(e) Amends section 503 of the Federal Food, Drug and Cosmetic Act to make the Act applicable to prescription drugs.

(f) Amends section 602 of the Federal Food, Drug, and Cosmetic Act to make cosmetics misbranded if they are packaged or labeled in violation of sections 3 or 4 of this Act.

Section 8—Federal preemption

State and local regulations of special packaging, which are not identical to Federal requirements, are preempted by Federal standards established by the Secretary.

Section 9—Effective date

This Act will become effective upon enactment. Standards for special packaging shall specify their effective date but such date shall not be prior to 180 days or later than 1 year from the date such regulation is final unless the Secretary finds that an earlier effective date is in the public interest and publishes his reasons therefor. No such standard shall be applicable to substances packaged prior to the effective date of the final regulation concerning such substance.

[p. 9]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., July 23, 1970

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your requests for reports on H.R. 6179, a bill "To amend the Federal Food, Drug, and Cosmetic Act to protect children and others from accidental death or injury by authorizing safety closures to be required for drug containers;" H.R. 6180, a bill "To amend the Hazardous Substances Act to provide safe packaging of toxic household substances in order to protect children;" H.R. 11783 and H.R. 14094, identical bills "To amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, and for other purposes;" and S. 2162, a bill "To provide for special packaging to protect children from serious personal injury or serious illness

resulting from handling, using, or ingesting household substances, and for other purposes."

[p. 15]

Household substances in violation of this Act would be considered misbranded under the Federal Hazardous Substances Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act and subject to the penalties imposed under these Acts. Whenever a standard established under this Act is in effect, no State or political subdivision may establish or continue in effect, with respect to any household substance, any standard for the special packaging or labeling of such substance which is not identical to the standard established under this Act.

[p. 17]

Sincerely,

ELLIOT L. RICHARDSON, ***Secretary***

Enclosure.

[p. 20]

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

SECTION 2(p) OF THE FEDERAL HAZARDOUS SUBSTANCES ACT

(p) The term "misbranded hazardous substance" means a hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable, for use in the household or by children, [which] *if the packaging or labeling of such substance is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if such* substance, except as otherwise provided by or pursuant to section 3, fails to bear a label—

(1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Secretary by regulation permits or requires the use of a recognized generic name; (C) the signal word "DANGER" on substances which are extremely flammable, corro-

sive, or highly toxic, (D) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards, such as "Flammable," "Combustible," "Vapor Harmful," "Causes Burns," "Absorbed Through Skin," or similar wording descriptive of the hazard; (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Secretary pursuant to section 3; (G) instruction, when necessary or appropriate, for first-aid treatment; (H) the word "poison" for any hazardous substance which is defined as "highly toxic" by subsection (h); (I) instructions for handling and storage of packages which require special care in handling or storage; and (J) the statement (i) "Keep out of the reach of children" or its practical equivalent, or, (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard, and

* * * * * * *

(2) on which any statements required under subparagraph (1) of this paragraph are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

[p. 23]

The term "misbranded hazardous substance" also includes a household substance as defined in section 2(2)(D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in paragraph 1 of section 2(f) of this Act and its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

* * * * * * *

SECTION 2Z (2) OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

z. The term "misbranded" shall apply—

(1) to any economic poison or device if its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(2) to any economic poison—

* * * * * * *

(h) if in the case of a plant regulator, defoliant, or desiccant when used as directed it shall be injurious to living man or other vertebrate animals, or vegetation to which it is applied, or to the person applying such economic poison: *Provided,* That physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when this is the purpose for which the plant regulator, defoliant, or desiccant was applied, in accordance with the label claims and recommendations [.]*; or*

(i) if its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

* * * * * * *

(n) If its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

* * * * * * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

* * * * * * *

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

* * * * * * *

[p. 24]

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) * * *

* * * * * * *

(b) (1) * * *

* * * * * * *

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g) [and (h)], *(h) and (p),* if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its

filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

* * * * * * *

MISBRANDED COSMETICS

SEC. 602. A cosmetic shall be deemed to be misbranded—

* * * * * * *

(f) If its packaging or labeling is in violation of an applicable regulation or order issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

* * * * * * *

PROVISIONS OF LAW REFERRED TO IN BILL

For the information of the Members the provisions of law referred to in section 2(2) of the bill which defines the term "household substance" are shown below:

SECTION 2(f) OF THE FEDERAL HAZARDOUS SUBSTANCES ACT (15 U.S.C. 1261(f))

DEFINITIONS

SEC. 2. For the purposes of this Act—

* * * * * * *

(f) The term "hazardous substance" means:

1. (A) Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably forseeable ingestion by children. [p. 25]

(B) Any substances which the Secretary by regulation finds, pursuant to the provisions of section 3(a), meet the requirements of subparagraph 1(A) of this paragraph.

(C) Any radioactive substance, if, with respect to such substance as used in a particular class of article or as packaged, the Secretary determines by regulation that the sub-

stance is sufficiently hazardous to require labeling in accordance with this Act in order to protect the public health.

(D) Any toy or other article intended for use by children which the Secretary by regulation determines, in accordance with section 3 (e) of this Act, presents an electrical, mechanical, or thermal hazard.

2. The term "hazardous substance" shall not apply to economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act, nor to foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, nor to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house, but such term shall apply to any article which is not itself an economic poisin within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazardous substance within the meaning of subparagraph 1 of this paragraph by reason of bearing or containing such an economic poison.

3. The term "hazardous substance" shall not include any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended, and regulations issued pursuant thereto by the Atomic Energy Commission.

SECTON 2a OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

(7 U.S.C. 135(a))

SEC. 2. For the purposes of this Act—

* * * * * * *

a. The term "economic poison" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living man or other animals, which the Secretary shall declare to be a pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.

SECTIONS 201 (f), (g), AND (i) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (21 U.S.C. 321)

SEC. 201. For the purposes of this Act—

* * * * * * *

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

[p. 26]

(g) (1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Phamacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

* * * * * * *

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

[p. 27]

1.6a (2) SENATE COMMITTEE ON COMMERCE

S. REP. No. 91-845, 91st Cong., 2d Sess. (1970)

POISON PREVENTION PACKAGING ACT

MAY 6 (legislative day, MAY 5), 1970.—Ordered to be printed

Mr. MOSS, from the Committee on Commerce, submitted the following

REPORT

[To accompany S. 2162]

The Committee on Commerce, to which was referred the bill (S. 2162) to amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

PURPOSE AND BRIEF SUMMARY

The purpose of S. 2162 is to reduce injuries to, and illnesses of, young children arising from ingestion of toxic or harmful substances customarily produced or distributed for sale for consumption, use, or storage by individuals in or about the household. The purpose of the bill is to be accomplished by requiring household substances which are accessible to young children and which may cause injury or illness to be contained in special packaging that is significantly difficult for children under six years of age to open or obtain a toxic or harmful amount of such substances within a reasonable time, but not difficult for normal adults to use properly. Special packaging is considered to be practicable because young children lack adult capabilities of strength, mastery of more complex operations and dexterity.

The scope of S. 2162 extends across all product lines and types to include all substances customarily produced or distributed for sale for consumption, use, or storage in or about the household. The bill authorizes the Secretary of Health, Education and Welfare to determine whether a substance should be contained in special packaging on the basis of its degree or nature of hazard to children. It empowers the Secretary after consultation with a [p. 1] technical advisory committee to establish performance standards for special packaging designed to protect young children against obtaining harmful amounts of such substance. Failure to conform to special packaging standards will result in the substance being deemed misbranded under applicable provisions of the Federal Hazardous Substances Act, the Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act and subject to the penalties therein prescribed.

Although special packaging, by definition, is not to be difficult for normal adults to use, the Committee recognized that elderly and handicapped persons (such as those with infirmities of the hand) may experience particular problems in opening special packaging. Accordingly, the Committee has provided that substances for which special packaging standards have been established may, nonetheless, be marketed in one size of ordinary container not complying with special packaging standard, or if dispensed pursuant to prescription, may be sold in ordinary packaging at the purchaser's request, for the use of the elderly and the handicapped. The single size container is to bear a label statement: "This package for households without young children."

The bill provides for creation of a technical advisory committee composed of members representative of industry, the public and the scientific and medical professions to advise the Secretary in making findings and establishing standards for substances.

Although the bill would become effective upon enactment, it provides that the effective date of regulations will be not sooner than 180 days after final promulgation of regulations. Morever, the bill provides that states may not establish or continue in effect standards not identical with federal standards.

[p. 2]

ANALYSIS OF THE BILL

TEXT OF THE BILL AS AMENDED

[S. 2162, 91st Cong., second session]

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL To amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, [That this Act may be cited as the "Poison Prevention Packaging Act of 1969".

[p. 4]

* * * * * * *

SEC. 6.

(b) Section 2(z) (2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(z)(2)) is amended by striking out the period at the end of paragraph (h) of such section and inserting in lieu thereof a semicolon and the word "or" and by adding at the end thereof a new paragraph as follows:

> *"(i) if its packaging or labeling is in violation of regulations issued pursuant to sections 3 and 4 of the Poison Prevention Packaging Act of 1970."*

[p. 8]

SECTION BY SECTION ANALYSIS

* * * * * * *

Section 6. This section sets forth amendments to the Federal Hazardous Substances Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act such that failure to comply with special packaging standards promulgated under the Poison Prevention Packaging Act results in packaging being "misbranded" and subject to the sanctions provided by the other applicable acts.

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill as reported are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

[p. 12]

SECTION 2(z) OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT AS AMENDED (7 U.S.C. 135 (z))

(z) The term "misbranded" shall apply—

(1) * * *

(2) to any economic poison—

* * * * * * *

(i) if its packaging or labeling is in violation of regulations issued pursuant to sections 3 and 4 of the Poison Prevention Packaging Act of 1970.

[p. 13]

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, D.C., October 11, 1969.

HON. WARREN G. MAGNUSON,
Chairman, Committe on Commerce,
U.S. Senate.

DEAR MR. CHAIRMAN: This is in reply to your request of September 24, 1969 for a report on S. 2162. The bill is entitled "To amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, and for other purposes."

The bill would amend the Federal Hazardous Substances Act to extend the provisions of the Act for protecting the public health and the safety of children. The bill would authorize the Secretary of Health, Education, and Welfare to promulgate regulations establishing standards for the packaging of any hazardous substance designed to prevent or substantially reduce the hazard of serious injury or serious illness to children likely to handle, use, or ingest any such hazardous substance. The term "package" is defined under the bill. The interstate shipment of any hazardous substance, as defined under the Act (15 U.S.C. 1261), would be prohibited unless the package complies with the standards established by the Secretary. The term "hazardous substance" as defined under the bill does not apply to economic poisons regulated by this Department under the Federal Insecticide, Fungicide, and Rodenticide Act as now provided for under the Federal Hazardous Substances Act. This exemption notwithstanding, Section 3(d)(1) contains provisions for establishing standards for the packaging of any hazardous substance, as defined under the bill, when the Secretary of Health, Education, and Welfare determines that the degree or nature of the hazard involved in the presence or use of any hazardous substance, as defined, is such that the objective of protecting the public health and safety of children requires special packaging.

This Department recommends the enactment of S. 2162 if amended as follows:

On p. 3, line 10, after the "comma" delete "the Federal Insecticide, Fungicide, and Rodenticide Act,".

On p. 3, line 12, after the word "law" insert the following "with the exception of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended".

A more detailed statement in support of this position is enclosed for your information.

This Department works closely with the Department of Health, Education, and Welfare on matters relating to pesticides. We will continue to coordinate activities relating to safe packaging standards for pesticides in protecting the health and safety of all persons using pesticides, especially children.

[p. 17]

The Bureau of the Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

CLIFFORD M. HARDIN,
Secretary of Agriculture.

EXPLANATION OF USDA POSITION ON S. 2162

The Department of Agriculture is responsible for administering the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This Act requires that all economic poisons moving in interstate commerce must be registered with this Department. In the registration process we are directly concerned with the avoidance of any kind of hazard involving the use of economic poisons, generally known as pesticides. We do not register a product until a determination is made that the product is both effective and safe for intended use according to directions on the product label. Labels that are easy to read and understand are a necessity. In March 1964, we strengthened our regulations with respect to labeling of registered products. Key warning and caution statements are required to be shown in a prominent place on the front panel of the pesticide label. The label must include the statement "Keep Out of Reach of Children" or its equivalent and a "signal" word–such as "Danger", "Warning" or "Caution"–which draws the user's attention to the necessity for handling the product with care. The registered label must be affixed to a package so as to be easily read.

The Act, as amended, does not presently include an affirmative provision specifically relating to packaging of pesticides. We do,

however, refuse or cancel registration of pesticides if it is determined that the form in which the product is marketed is such that it may be considered an "attractive nuisance" especially to children or that it may be a hazard in some other manner. For example, registration has been refused or cancelled for rodent baits which have the appearance of cookies or candy, and ant baits in bottle caps. Also, the size of the package is considered. Limitations on package sizes of the more hazardous products are made in order to avoid or preclude purchase by the homeowner or inexperienced user. We intend to continue pursuing this aspect of pesticide registration to the fullest extent possible under our present authority.

In addition, we are considering a legislative proposal to amend the FIFRA in several respects.One of these is to strengthen the present authority regarding packaging of pesticides required to be registered. With respect to pesticides, this Department's proposal would cover more types of products than those which would include "the degree or nature of the hazard involved in the presence or use of any hazardous substance in or around households is such that the objective of the protection of the public health and safety of children requires the special packaging thereof".

Pesticides regulated under the FIFRA are now exempt from the Hazardous Substances Act (15 U.S.C. 1261(f)(2)). This Department recommends that this exemption be continued with [p. 18] respect to safe packaging requirements on the basis that (a) similar authority is being considered for packaging of pesticides by amendment to FIFRA; and (b) that enforcement of safe packaging requirements can be conducted more effectively by this Department as a condition of registration required in order for pesticide products to move in interstate commerce. [p. 19]

1.6a (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 91-1755, 91st Cong., 2d Sess. (1970)

THE POISON PREVENTION PACKAGING ACT OF 1970

DECEMBER 15, 1970.—Ordered to be printed

Mr. STAGGERS, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 2162]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 2162) to pro-

vide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

SECTION 1. ***This Act may be cited as the "Poison Prevention Packaging Act of 1970".***

SEC. 2. ***For the purpose of this Act—***

(1) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(2) The term "household substance" means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is—

> ***(A) a hazardous substance as that term is defined in section 2(f) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f));***
>
> ***(B) an economic poison as that term is defined in section 2a of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(a));***
>
> ***(C) a food, drug, or cosmetic as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act. (21 U.S.C. 321); or***
>
> ***(D) a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.***

[p. 1]

(3) The term "package" means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, and, for purposes of section 4(a) (2) of this Act, also means any outer container or wrapping used in the retail display of any such substance to consumers. Such term does not include—

> ***(A) any shipping container or wrapping used solely for the transportation of any household substance in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or***

(B) any shipping container or outer wrapping used by retailers to ship or deliver any household substance to consumers unless it is the only such container or wrapping.

(4) The term "special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

(5) The term "labeling" means all labels and other written, printed, or graphic matter (A) upon any household substance or its package, or (B) accompanying such substance.

SEC. 3. *(a) The Secretary, after consultation with the technical advisory committee provided for in section 6 of this Act, may establish in accordance with the provisions of this Act, by regulation, standards for the special packaging of any household substance if he finds that—*

(1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

(2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.

(b) In establishing a standard under this section, the Secretary shall consider—

(1) the reasonableness of such standard;

(2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) the manufacturing practices of industries affected by his Act; and

(4) the nature and use of the household substance.

(c) In carrying out this Act, the Secretary shall publish his findings, his reasons therefor, and citation of the sections of statutes which authorize his action.

(d) Nothing in this Act shall authorize the Secretary to prescribe specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 4(a)(2) of this Act, labeling. In the case of a household substance for which special

packaging is required pursuant to a regulation under this section, the Secretary may in such regulation prohibit the packaging of [p. 2] *such substance in packages which he determines are unnecessarily attractive to children.*

SEC. 4. *(a) For the purpose of making any household substance which is subject to a standard established under section 3 readily available to elderly or handicapped persons unable to use such substance when packaged in compliance with such standard, the manufacturer or packer, as the case may be, may package any household substance, subject to such a standard, in packaging of a single size which does not comply with such standard if—*

(1) the manufacturer (or packer) also supplies such substance in packages which comply with such standard; and

(2) the packages of such substance which do not meet such standard bear conspicuous labeling stating: "This package for households without young children"; except that the Secretary may by regulation prescribe a substitute statement to the same effect for packaging too small to accommodate such labeling.

(b) In the case of a household substance which is subject to such a standard and which is dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner authorized to prescribe, such substance may be dispensed in noncomplying packages only when directed in such order or when requested by the purchaser.

(c) In the case of a household substance subject to such a standard which is packaged under subsection (a) in a noncomplying package, if the Secretary determines that such substance is not also being supplied by a manufacturer (or packer) in popular size packages which comply with such standard, he may, after giving the manufacturer (or packer) an opportunity to comply with the purposes of this Act, by order require such substance to be packaged by such manufacturer (or packer) exclusively in special packaging complying with such standard if he finds, after opportunity for hearing, that such exclusive use of special packaging is necessary to accomplish the purposes of this Act.

SEC. 5. *(a) Proceedings to issue, amend, or repeal a regulation prescribing a standard under section 3 shall be conducted in accordance with the procedures prescribed by section 553 (other than paragraph (3)(B) of the last sentence of subsection (b) of such section) of title 5 of the United States Code unless the Secretary elects the procedures prescribed by subsection (e) of section 701 of* *the Federal Food, Drug, and Cosmetic Act, in which event such subsection and subsections (f) and (g) of such section 701 shall apply to such proceedings. If the Secretary makes such election, he shall publish that fact with the proposal required to be published under paragraph (1) of such subsection (e).*

(b) (1) in the case of any standard prescribed by a regulation issued in accordance with section 553 of title 5 of the United States Code, any person who will be adversely affected by such a standard may, at any time prior to the 60th day after the regulation prescribing such standard is issued by the Secretary, file a petition with the United States Court of Appeals for the circuit in which such person resides or has his principal place of business for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the [p. 3] *Secretary based his standard, as provided in section 2112 of title 28 of the United States Code.*

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there was no opportunity to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary in a hearing or in such other manner, and upon such terms and conditions as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original standard, with the return of such additional evidence.

(3) Upon the filing of the petition under paragraph (1) of this subsection the court shall have jurisdiction to review the standard of the Secretary in accordance with subparagraphs (A), (B), (C), and (D) of paragraph (2) of section 706 of title 5 of the United States Code. If the court ordered additional evidence to be taken under paragraph (2) of this subsection, the court shall also review the Secretary's standard to determine if, on the basis of the entire record before the court pursuant to paragraphs (1) and (2) of this subsection, it is supported by substantial evidence. If the court finds the standard is not so supported, the court may set it aside.

(4) With respect to any standard reviewed under this subsection,

the court may grant appropriate relief pending conclusion of the review proceedings, as provided in section 705 of such title 5.

(5) The judgment of the court affirming or setting aside, in whole or in part, any such standard of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28 of the United States Code.

SEC. 6. *(a) For the purpose of assisting in carrying out the purposes of this Act, the Secretary shall appoint a technical advisory committee, designating a member thereof to be chairman, composed of not more than eighteen members who are representative of (1) the Department of Health, Education, and Welfare, (2) the Department of Commerce, (3) manufacturers of household substances subject to this Act, (4) scientists with expertise related to this Act and licensed practitioners in the medical field, (5) consumers, and (6) manufacturers of packages and closures for household substances. The Secretary shall consult with the technical advisory committee in making findings and in establishing standards pursuant to this Act.*

(b) Members of the technical advisory committee who are not regular full-time employees of the United States shall, while attending meetings of such committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding $100 per diem, including traveltime, and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

SEC. 7. *(a) Section 2(p) of the Federal Hazardous Substances Act (15 U.S.C. 1261(p)) is amended—*

[p. 4]

(1) by striking out "which substance" in the part preceding paragraph (1) and inserting in lieu thereof "if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if such substance"; and

(2) by adding the following after and below paragraph (2): "The term 'misbranded hazardous substance' also includes a household substance as defined in section 2(2)(D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in paragraph 1 of section 2(f) of this Act and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(b) Section 2z(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(z)(2)) is amended by striking out the period at the end of paragraph (h) of such section and inserting in lieu thereof "; or" and by adding at the end thereof a new paragraph as follows:

> *"(i) if its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."*

(c) Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end thereof a new paragraph as follows:

"(n) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(d) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end thereof a new paragraph as follows:

"(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

(e) Section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(2)) is amended by striking out "and (h)" and inserting in lieu thereof ", (h), and (p)".

(f) Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amended by adding at the end thereof a new paragraph as follows:

"(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970."

SEC. 8. *Whenever a standard established by the Secretary under this Act applicable to a household substance is in effect, no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the standard established under section 3 (and any exemption therefrom and requirement related thereto) of this Act.*

SEC. 9. *This Act shall take effect on the date of its enactment. Each regulation establishing a special packaging standard shall specify the date such standard is to take effect which date shall not be sooner than one hundred and eighty days or later than one year from the date such regulation is final, unless the Secretary,*

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for good cause found, determines that an earlier effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier date shall apply. No such standard shall be effective as to household substances subject to this Act packaged prior to the effective date of such final regulation.

And the House agree to the same.

HARLEY O. STAGGERS,
JOHN E. MOSS,
JOHN M. MURPHY,
HASTINGS KEITH,
Managers on the Part of the House.
WARREN G. MAGNUSON,
PHILIP A. HART,
FRANK E. MOSS,
JAMES B. PEARSON,
CHARLES E. GOODELL,
Managers on the Part of the Senate.

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STATEMENT OF THE MANAGERS ON THE PART OF THE HOUSE

The managers on the part of the House at the conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 2162) to provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes, submit the following statement in explanation of the effect of the action agreed upon by the conferees and recommended in the accompanying conference report:

The House amendment to the bill struck out all of the Senate bill after the enacting clause and inserted a substitute amendment. The committee of conference has agreed to a substitute for both the Senate bill and the House amendment to the bill. Except for technical, clarifying, and conforming changes, the following statement explains the differences between the House amendment and the substitute agreed to in conference.

The conference substitute is identical to the bill as amended by the House except for the provision in section 4(a) authorizing manufacturers (or packers) of household substances subject to special packaging requirements to package such substances in packages not complying with such requirements for the purpose of making such substances readily available to the elderly and handicapped unable to use such substances in packages complying with such requirements.

In section 4(a), as amended by the House, the manufacturer (or packer) of a household substance subject to a special packaging requirement was given similar authority to package such a substance in noncomplying packages if he also packaged such substance in at least one package size complying with such standard and if the noncomplying packages were labeled to show that there were complying packages which should be used in households with young children. Thus, under the House version, most of the packages used in the marketing of such substances could be noncomplying packages. Complying packaging could have been the exception to general marketing practices.

Section 4(a) of the conference substitute is designed to make substances subject to special packaging requirements available to the elderly and handicapped in packages which do not unnecessarily hinder them in their use of such substances. A manufacturer (or packer) is permitted under such section to use for such a substance one size of packaging which does not meet the special packaging requirements if he also supplies the substance in packaging which complies with the requirements. In addition, the noncomplying packaging must be labeled to show it is not for households with young children.

It is expected that specially packaged substances will be the rule rather than the exception for substances regulated under this legislation. Also, it is expected that manufacturers (or packers) will not

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exact a premium price for specially packaged substances and will make every effort to assure the adequate distribution and advertisement of specially packaged substances so that the public will become acquainted with special packaging and familiar with its operation. Since the purpose of this section is to assist the elderly and handicapped, it is expected that the manufacturer (or packers) will use noncomplying packaging only when the required special packaging is of a kind that will create significant difficulty in use for the elderly and handicapped, and that manufacturers (or packers) will in using noncomplying packaging choose package sizes most likely to be used by the elderly and handicapped.

Although it has been pointed out that the majority of households do not contain young children, it was felt that, in order to adequately protect young children, the marketing in complying packages of substances subject to special packaging requirements had to be made the general marketing practice.

Section 4(b) of the conference substitute is identical to the House amendment and provides that in the case of household substances which are dispensed only upon prescription such substances (if subject to special packaging requirements) may be dispensed in noncomplying packages only when directed in the prescription or when requested by the purchaser.

Section 4(c) of the conference substitute is the same as section 4(b) of the House version and authorizes the Secretary to require exclusive use of special packaging for substances if (1) he determines that the substance is not being supplied by the manufacturer (or packer) in popular sizes of special packages; and (2) after giving the manufacturer (or packer) an opportunity to comply with the purposes of this act, he finds, after opportunity for hearing, that exclusive use of special packaging is necessary to accomplish the purposes of this act.

The legislation as passed by the Senate contained a special provision (section 3(e)) authorizing the Secretary to exempt categories of substances subject to special packaging requirements. That special provision was not contained in the House version and is not contained in the conference substitute because the Secretary may provide such exemptions while prescribing such special packaging requirements. In addition, if the Secretary wishes to make such an exemption after he has prescribed special packaging requirements, he may use the informal rulemaking authority provided in section 5 of the conference substitute to amend the regulation prescribing such requirement.

HARLEY O. STAGGERS,
JOHN E. MOSS,
JOHN M. MURPHY,
HASTINGS KEITH,
Managers on the Part of the House.

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1.6a (4) CONGRESSIONAL RECORD, VOL. 116 (1970)

1.6a (4) (a) May 11: Considered and passed Senate, pp. 14796–14798

[No Relevant Discussion on Pertinent Section]

1.6a (4) (b) Dec. 7: Considered and passed House, amended, pp. 40188–40193

[No Relevant Discussion on Pertinent Section]

1.6a (4) (c) Dec. 16: Senate and House agreed to conference report, pp. 41729–41730, 41948

[No Relevant Discussion on Pertinent Section]

1.6b FEDERAL ENVIRONMENTAL PESTICIDE CONTROL ACT OF 1972

October 21, 1972, P.L. 92–516, §3(3), 86 Stat. 998

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, **That this Act may be cited as the "Federal Environmental Pesticide Control Act of 1972".**

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AMENDMENTS TO OTHER ACTS

SEC. 3. The following Acts are amended by striking out the terms "economic poisons" and "an economic poison" wherever they appear and inserting in lieu thereof "pesticides" and "a pesticide" respectively:

* * * * * *

(2) The Poison Prevention Packaging Act, as amended (15 U.S.C. 1471 et seq.);

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* * * * * *

1.6b (1) HOUSE COMMITTEE ON AGRICULTURE

H.R. REP. No. 92–511, 92d Cong. 1st Sess. (1971)

[No Relevant Discussion on Pertinent Section]

1.6b (2) SENATE COMMITTEE ON AGRICULTURE AND FORESTRY

S. REP. No. 92–838, 92 Cong., 2d Sess. (1972)

[No Relevant Discussion on Pertinent Section]

1.6b (3) SENATE COMMITTEE ON COMMERCE

S. REP. No. 92–970, 92d Cong., 2d Sess. (1972)

[No Relevant Discussion on Pertinent Section]

1.6b (4) COMMITTEE OF CONFERENCE

H.R. REP. No. 92–1540, 92d Cong., 2d Sess. (1972)

[No Relevant Discussion on Pertinent Section]

1.6b (5) CONGRESSIONAL RECORD:

1.6b(5)(a) VOL. 117 (1971): Nov. 8, 9: Considered and passed House

1.6b(5)(b) VOL. 118 (1972): Sept. 26: Considered and passed Senate, amended

[No Relevant Discussion on Pertinent Section]

1.6b(5)(c) VOL. 118 (1972), Oct. 5: Senate agreed to conference report

[No Relevant Discussion on Pertinent Section]

1.6b(5)(d) VOL. 118 (1972), Oct. 12: House agreed to conference report.

[No Relevant Discussion on Pertinent Section]

1.7 HEARINGS; PRESIDING EMPLOYEES; POWERS AND DUTIES; BURDEN OF PROOF; EVIDENCE; RECORD AS A BASIS OF DECISION, AS REVISED

5 U.S.C. §556(c) (1966).

[Referred to in 7 U.S.C. §135b(c), 21 U.S.C. §246a (d) (5)]

ADMINISTRATIVE PROCEDURE ACT

§ 556. Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision

(a) This section applies, according to the provisions thereof, to hearings required by section 553 or 554 of this title to be conducted in accordance with this section.

(b) There shall preside at the taking of evidence—

(1) the agency;

(2) one or members of the body which comprises the agency; or

(3) one or more hearing examiners appointed under section 3105 of this title.

This subchapter does not supercede the conduct of specified classes of proceedings, in whole or in part, by or before boards or other employees specially provided for by or designated under statute. The functions of presiding employees and of employees participating in decisions in accordance with section 557 of this title shall be conducted in an impartial manner. A presiding or participating employee may at any time disqualify himself. On the filing in good faith of a timely and sufficient affidavit of personal bias or other disqualification of a presiding or participating employee, the agency shall determine the matter as a part of the record and decision in the case.

(c) Subject to published rules of the agency and within its powers, employees presiding at hearings may—

(1) administer oaths and affirmations;

(2) issue subpenas authorized by law;

(3) rule on offers of proof and receive relevant evidence;

(4) take depositions or have depositions taken when the ends of justice would be served;

(5) regulate the course of the hearing;

(6) hold conferences for the settlement or simplification of the issues by consent of the parties;

(7) dispose of procedural requests or similar matters;

(8) make or recommend decisions in accordance with section 557 of this title; and

(9) take other action authorized by agency rule consistent with this subchapter.

(d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(e) The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 of this title and, on payment of lawfully prescribed costs, shall be made available to the parties. When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.

Pub.L. 89–554, Sept. 6, 1966, 80 Stat. 386.

1.7a ADMINISTRATIVE PROCEDURE IN HEARINGS ACT

June 11, 1946, P.L. 79–404, 60 Stat. 241

HEARINGS

SEC. 7. In hearings which section 4 or 5 requires to be conducted pursuant to this section—

(a) PRESIDING OFFICERS.—There shall preside at the taking of evidence (1) the agency, (2) one or more members of the body which comprises the agency, or (3) one or more examiners appointed as provided in this Act; but nothing in this Act shall be deemed to supersede the conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute. The functions of all presiding officers and of officers participating in decisions in conformity with section 8 shall be conducted in an impartial manner. Any such officer may at any time withdraw if he deems himself disqualified; and, upon the filing in good faith of a timely and sufficient affidavit of personal bias or disqualification of any such officer, the agency shall determine the matter as a part of the record and decision in the case.

(b) HEARING POWERS.—Officers presiding at hearings shall have authority, subject to the published rules of the agency and within its powers, to (1) administer oaths and affirmations, (2) issue subpenas authorized by law, (3) rule upon offers of proof and receive relevant evidence, (4) take or cause depositions to be taken whenever the ends of justice would be served thereby, (5) regulate the course of the hearing, (6) hold conferences for the settlement or simplification of the issues by consent of the parties, (7) dispose of procedural requests or similar matters, (8) make decisions or recommend decisions in conformity with section 8, and (9) take any other action authorized by agency rule consistent with this Act.

(c) EVIDENCE.—Except as statutes otherwise provide, the proponent of a rule or order shall have the burden of proof. Any oral or documentary evidence may be received, but every agency shall as a matter of policy provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence and no sanction shall be imposed or rule or order be issued except upon consideration of the whole record or such portions thereof as may be cited by any party and as supported by and in accordance with the reliable, probative, and substantial evidence. Every party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses any agency may, where the interest of any party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(d) RECORD.—The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, shall [p. 241] constitute the exclusive record for decision in accordance with

section 8 and, upon payment of lawfully prescribed costs, shall be made available to the parties. Where any agency decision rests on official notice of a material fact not appearing in the evidence in the record, any party shall on timely request be afforded an opportunity to show the contrary.

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1.7a (1) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 752, 79th Cong., 1st Sess. (1945)

ADMINISTRATIVE PROCEDURE ACT

NOVEMBER 19 (legislative day, OCTOBER 29), 1945.—Ordered to be printed

Mr. MCCARRAN, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 7]

The Committee on the Judiciary, to whom was referred the bill (S. 7), to improve the administration of justice by prescribing fair administrative procedure, having considered the same, reports favorably thereon, with an amendment, and recommend that the bill do pass, as amended.

There is a widespread demand for legislation to settle and regulate the field of Federal administrative law and procedure. The subject is not expressly mentioned in the Constitution, and there is no recognizable body of such law, as there is for the courts in the Judicial Code. There are no clearly recognized legal guides for either the public or the administrators. Even the ordinary operations of administrative agencies are often difficult to know. The Committee on the Judiciary is convinced that, at least in essentials, there should be some simple and standard plan of administrative procedure.

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III. STRUCTURE OF THE BILL

The bill, as reported, is not a specification of the details of administrative procedure, nor is it a codification of administrative law. Instead, out of long consideration and in the light of the studies heretofore mentioned, there has been framed an outline of minimum basic essentials. Figure 2 on page 9 diagrams the bill.

The bill is designed to afford parties affected by administrative powers a means of knowing what their rights are and how they

may be protected. By the same token, administrators are provided with a simple course to follow in making administrative determinations. The jurisdiction of the courts is clearly stated. The bill thus provides for public information, administrative operation, and judicial review.

SUBSTANCE OF THE BILL.—What the bill does in substance may be summarized under four headings:

1. It provides the agencies must issue as rules certain specified information as to their organization and procedure, and also make available other materials of administrative law (sec. 3).
2. It states the essentials of the several forms of administrative proceedings (secs. 4, 5, and 6) and the limitations on administrative powers (sec. 9).
3. It provides in more detail the requirements for administrative hearings and decisions in cases in which statutes require such hearings (secs. 7 and 8).
4. It sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong (sec. 10).

The first of these is basic, because it requires agencies to take the initiative in informing the public. In stating the essentials of the different forms of administrative proceedings, it carefully distinguishes between the so-called legislative functions of administrative agencies (where they issue general regulations) and their judicial functions (in which they determine rights or liabilities in particular cases).

The bill provides quite different procedures for the "legislative" and "judicial" functions of administrative agencies. In the "rule making" (that is, "legislative") function it provides that, with certain exceptions, agencies must publish notice and at least permit interested parties to submit their views in writing for agency consideration before issuing general regulations (sec. 4). No hearings are required by the bill unless statutes already do so in a particular case. Similarly, in "adjudications" (that is, the "judicial" function) no agency hearings are required unless statutes already do so, but in the latter case the mode of hearing and decision is

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prescribed (sec. 5). Where existing statutes require that either general regulations (called "rules" in the bill) or particularized adjudications (called "orders" in the bill) be made after agency hearing or opportunity for such hearing, then section 7 spells out the minimum requirements for such hearings, section 8 states how decisions shall be made thereafter, and section 11 provides for examiners to preside at hearings and make or participate in decisions.

While the administrative power and procedure provisions of sections 4 through 9 are law apart from court review, the provisions for judicial review provide parties with a method of enforcing their rights in a proper case (sec. 10). However, it is expressly provided that the judicial review provisions are not operative where statutes otherwise preclude judicial review or where agency action is by law committed to agency discretion.

KINDS OF PROVISIONS.—The bill may be said to be composed of five types of provisions:

1. Those which are largely formal such as the sections setting forth the title (sec. 1), definitions (sec. 2), and rules of construction (sec. 12).
2. Those which require agencies to publish or make available information on administrative law and procedure (sec. 3).
3. Those which provide for different kinds of procedures such as rule making (sec. 4), adjudications (sec. 5), and miscellaneous matters (sec. 6) as well as for limitations upon sanctions and powers (sec. 9).
4. Those which provide more of the detail for hearings (sec. 7) and decisions (sec. 8) as well as for examiners (sec. 11).
5. Those which provide for judicial review (sec. 10).

The bill is so drafted that its several sections and subordinate provisions are closely knit. The substantive provisions of the bill should be read apart from the purely formal provisions and minor functional distinctions. The definitions in section 2 are important, but they do not indicate the scope of the bill since the subsequent provisions make many functional distinctions and exceptions. The public information provisions of section 3 are of the broadest application because, while some functions and some operations may not lend themselves to formal procedure, all administrative operations should as a matter of policy be disclosed to the public except as secrecy may obviously be required or only internal agency "housekeeping" arrangements may be involved. Sections 4 and 5 prescribe the basic requirements for the making of rules and the adjudication of particular cases. In each case, where other statutes require opportunity for an agency hearing, sections 7 and 8 set forth the minimum requirements for such hearings and the agency decisions thereafter while section 11 provides for the appointment and tenure of examiners who may participate. Section 6 prescribes the rights of private parties in a number of miscellaneous respects which may be incidental to rule making, adjudication, or the exercise of any other agency authority. Section 9 limits sanctions, and section 10 provides for judicial review.

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* * * * * * *

(b) PROCEDURES.—*After such notice, the agency must afford interested persons an opportunity to participate in the rule making at least to the extent of submitting written data, views, or argument; and, after consideration of such presentations, the agency must incorporate in any rules adopted a concise general statement of their basis and purpose. However, where other statutes require rules to be made after hearing, the requirements of sections 7 and 8 (relating to public hearings and decisions thereon) apply in place of the provisions of this subsection.*

This subsection states, in its first sentence, the minimum requirements of public rule making procedure short of statutory hearing. Under it agencies might in addition confer with industry advisory committees, consult organizations, hold informal "hearings," and the like. Considerations of practicality, necessity, and public interest as discussed in connection with subsection (a) will naturally govern the agency's determination of the extent to which public proceedings

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(c) RULE AND RULE MAKING.—*"Rule" is defined as any agency statement of general applicability designed to implement, interpret or prescribe law, policy, organization, procedure, or practice requirements. "Rule making" means agency process for the formulation, amendment, or repeal of a rule and includes any prescription for the future of rates, wages, financial structures, etc., etc.*

The definition of "rule" is important because it prescribes the kind of operation that is subject to section 4 rather than section 5. The specifications of the activities that are involved in rule making is included in order to comprehend them beyond any possible question. They are defined as rules to the extent that, whether of general or particular applicability, they formally prescribe a course of conduct for the future rather than merely pronounce existing rights or liabilities. It should be noted that rule making is exempted from some of the general requirements of sections 7 and 8 relating to the details of hearings and decisions.

(d) ORDER AND ADJUDICATION.—*"Order" means the final disposition of any matter, other than rule making but including licensing, whether or not affirmative, negative, or declaratory in form. "Adjudication" means the agency process for the formulation of an order.*

The term "order" is defined to exclude rules. "Licensing" is specifically included to remove any possible question at the outset. Licenses involve a pronouncement of present rights of named parties although they may also prescribe terms and conditions for future observance. It should be noted, however, that licensing is exempted from some of the provisions of sections 5, 7, and 8 relating to hearings and decisions.

(e) LICENSE AND LICENSING.—*"License" is defined to include any form of required official permission such as certificate, charter, etc. "Licensing" is defined to include agency process respecting the grant, renewal, modification, denial, revocation, etc., of a license.*

This definition supplements subsection (d). Later provisions of the bill distinguish between initial lincenses and renewals or other licensing proceedings. A further distinction might have been drawn between licenses for a term, such as radio licenses, and those of indefinite duration, such as certificates of convenience and necessity.

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should go. Matters of great import, or those where the public submission of facts will be either useful to the agency or a protection to the public, should naturally be accorded more elaborate public procedures. The agency must analyze and consider all relevant matter presented. The required statement of the basis and purpose of rules issued should not only relate to the data so presented but with reasonable fullness explain the actual basis and objectives of the rule.

(c) EFFECTIVE DATES.—*The required publication or service of any substantive rule must be made not less than 30 days prior to its effective date except (1) as otherwise provided by the agency for good cause found and published or (2) in the case of rules recognizing exemption or relieving restriction, interpretative rules, and statements of policy.*

This subsection does not provide procedures alternative to notice and other public proceedings required by the prior subsections of this section. Nor does it supersede the provisions of subsection (d) of this section. Where public procedures are omitted as authorized in certain cases, subsection (c) does not thereby become inoperative. It will afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take any other action which the issuance of rules may prompt. While certain named kinds of rules are not necessarily subject to the deferred effective date provided, it does not thereby follow that agencies are required to make such excepted types of rules operative with less notice or no notice but, instead, agencies are given discretion in those cases to fix such future effective date as they may find advisable. The other exception, upon good cause found and published, is not an "escape clause" which may be arbitrarily exercised but requires legitimate grounds supported in law and fact by the required finding. Moreover, the specification of a 30-day deferred effective date is not to be taken as a maximum, since there may be cases in which good administration or the convenience and necessity of the persons subject to the rule reasonably requires a longer period.

(d) PETITIONS.—*Every agency is required to accord any interested person the right to petition for the issuance, amendment, or repeal of a rule.*

This subsection applies not merely to effective rules existing at any time but to proposed or tentative rules. Where the latter are published, agencies should receive petitions for modification because that is one of the purposes of publishing proposed or tentative rules. Where such petitions are made, the agency must fully and promptly consider them, take such action as may be required, and pursuant to section 6 (d) notify the petitioner in case the request is denied. The agency may either grant the petition, undertake public rule making proceedings as provided by subsections (a) and (b) of this section, or deny the petition. The taking or denial of action would have the same effect and consequences as the taking or denial of action where, under presently existing legislation, the equivalent of a right of petition is recognized in interested persons. The mere filing of a petition does not require an agency to grant it, or to hold a hearing, or engage in any other public rule making proceedings. The refusal of an agency to grant the petition or to hold rule making proceedings, therefore, would not per se be subject to judicial reversal. However, the facts or considerations brought to the attention of an agency by such a petition might be such as to require the agency to act to prevent the rule from continuing or becoming vulnerable upon judicial

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review, through declaratory judgment or other procedures pursuant to section 10.

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(b) PROCEDURE.—*The agency is required first to afford parties an opportunity for the settlement or adjustment of issues (where time, the nature of the proceeding, and the public interest permit) followed, to the extent that issues are not so settled, by hearing and decision under sections 7 and 8.*

The preliminary settlement-by-consent provision of this subsection is of the greatest importance. Such adjustments may go to the whole or any part of any case. The limitation of the requirement to cases in which "time, the nature of the proceeding, and the public interest permit" does not mean that formal proceedings, to the exclusion of prior opportunity for informal settlement, lie in the discretion of any agency irrespective of the facts, legal situation presented, or practical aspects of the case. It does not mean that agencies have an arbitrary choice, or that they may consult their mere preference or convenience. It is intended to exempt only situations in which, for example, (1) time is unavoidably lacking, (2) the nature of the proceeding is such that for example (as in some forms of rule making) the great number of parties or possible parties makes it unlikely that any adjustment could be reached, and (3) the administrative function requires immediate execution in order to protect the tangible and demonstrable requirements of public interest.

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SEC. 6. ANCILLARY MATTERS.—*The provisions of section 6 relating to incidental or miscellaneous rights, powers, and procedures do not override contrary provisions in other parts of the bill.*

The purpose of this introductory exception, which reads "except as otherwise provided in this act," is to limit, for example, the right of appearance provided in subsection (a) so as not to authorize improper ex parte conferences during formal hearings and pending formal decisions under sections 7 and 8.

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SEC. 7. HEARINGS.—*Section 7 relating to agency hearings applies only where hearings are required by sections 4 or 5.*

As heretofore stated in connection with sections 4 and 5, the bill requires no hearings unless other statutes contain such a requirement in particular cases of either rule making or adjudication. This section 7, therefore, is merely supplementary to sections 4 or 5 in the relevant cases.

(a) PRESIDING OFFICERS.—*The hearing must be held either by the agency, a member or members of the board which comprises it, one or more examiners, or other officers specially provided for in*

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or designated by other statutes. All presiding and deciding officers are to operate impartially. They may at any time withdraw if they deem themselves disqualified and, upon the filing of a proper affidavit of personal bias or disqualification against them, the agency is required to determine the matter as a part of the record and decision in the case.

This subsection provides two mutually exclusive methods of hearing—by the agency itself (or one or more of its members) or by subordinate officers. A third kind of hearing officer recognized in this subsection is one specially provided for or named in other statutes. Whoever presides is subject to the remaining provisions of the bill. They must conduct the hearing in a strictly impartial manner, rather than as the representative of an investigative or prosecuting authority, but this does not mean that they do not have the authority and duty—as a court does—to make sure that all necessary evidence is adduced and to keep the hearing orderly and efficient. The provision for affidavits of bias or personal disqualification requires a decision thereon by the agency in, and as a part of, the case; it thereby becomes subject to administrative and judicial review. That decision might be made upon the affidavit alone, as for example, the protest might be dismissed as insufficient on its face. The agency itself may hear any relevant argument or facts, or it may designate an examiner to do so. The effect which bias or disqualification shown upon the record might have would be determined by the ordinary rules of law and the other provisions of this bill. If it appeared or were discovered late, it would have the effect—where issues of fact or discretion were important and the conduct and demeanor of witnesses relevant in determining them—of rendering the recommended decisions or initial decisions of such officers invalid. This consequence will require agencies and examiners themselves to take care that they do not sit where subject to disqualification or conduct themselves in a manner which will invalidate the proceedings.

(b) HEARING POWERS.—*Presiding officers, subject to the rules of procedure adopted by the agency and within its powers, have authority to (1) administer oaths, (2) issue such subpenas as are authorized by law, (3) receive evidence and rule upon offers of proof, (4) take depositions or cause depositions to be taken, (5) regulate the hearing, (6) hold conferences for the settlement or simplification of the issues, (7) dispose of procedural requests, (8) make decisions or recommended decisions under section 8 of the bill, and (9) exercise other authority as provided by agency rule consistent with the remainder of the bill.*

This subsection does not expand the powers of agencies. It is designed to assure that the presiding officer will perform a real function rather than serve merely as a notary or policeman. He would have and should independently exercise all the powers numbered in the subsection. The agency itself—which must ultimately either decide the case, or consider reviewing it, or hear appeals from the examiner's decision—should not in effect conduct hearings from behind the scenes where it cannot know the detailed happenings in the hearing room and does not hear or see the private parties.

(c) EVIDENCE.—*Except as statutes otherwise provide, the proponent of a rule or order has the burden of proof. While any evidence may be received, as a matter of policy agencies are required to provide for the exclusion of irrelevant and unduly repetitious evidence and no sanction may be imposed or rule or order be* [p. 21] *issued except as supported by relevant, reliable, and probative evidence. Any party may present his case or defense by oral or documentary evidence, submit rebuttal evidence, and conduct reasonable cross-examination. However, in the case of rule making or determining applications for initial licenses, the agency may adopt procedures for the submission of evidence in written form so far as the interest of any party will not be prejudiced thereby.*

That the proponent of a rule or order has the burden of proof means not only that the party initiating the proceeding has the general burden of coming forward with a prima facie case but that other parties, who are proponents of some different result, also for that purpose have a burden to maintain. Similarly the requirement that no sanction be imposed or rule or order be issued except upon evidence of the kind specified means that the proponents of a denial of relief must sustain such denial by that kind of evidence. For example, credible and credited evidence submitted by the applicant for a license may not be ignored except upon the requisite kind and quality of contrary evidence. No agency is authorized to stand mute and arbitrarily disbelieve credible evidence. Except as applicants for a license or other privilege may be required to come forward with a prima facie showing, no agency is entitled to presume that the conduct of any person or status of any enterprise is unlawful or improper.

The second and primary sentence of the subsection is framed on the theory that an administrative hearing is to be compared with an equity proceeding in the courts. The mere admission of evidence is not to be taken as prejudicial error (there being no lay jury to be protected from improper influence) although irrelevant and unduly repetitious evidence is to be excluded as a matter of efficiency and good practice; and no finding or conclusion may be entered except upon evidence which is plainly of the requisite materiality and competence; that is, "relevant, reliable, and probative evidence." Thus while the exclusionary "rules of evidence" do not apply except as the agency may as a matter of good practice simplify the hearing and record by excluding obviously improper or unnecessary evidence, the standards and principles of probity and reliability of evidence must be the same as those prevailing in courts of law or equity in nonadministrative cases. There are no real rules of probity and reliability even in courts of law, but there are certain standards and principles—usually applied tacitly and resting mainly upon common sense—which people engaged in the conduct of responsible affairs instinctively understand and act upon. They may vary with the circumstances and kind of case, but they exist and must be rationally applied. These principles, under this subsection, are to govern in administrative proceedings.

The right of cross-examination extends, in a proper case, to written evidence submitted pursuant to the last sentence of the subsection as well as to cases in which oral or documentary evidence is received in open hearing. Even in the latter case, subject to the appropriate safeguards, technical data may as a matter of convenience be reduced to writing and introduced as in courts. The written evidence provision of the last sentence of the subsection is designed to cover situations in which, as a matter of general rule or practice, the submission of the whole or substantial portions of the evidence in a case is done in written form. In those situations, however, the provision limits the practice to

[p. 22]

specified classes of cases and, even then, only where and to the extent that "the interest of any party will not be prejudiced thereby." To the extent that cross-examination is necessary to bring out the truth, the party should have it. Also, an adequate opportunity must be provided for a party to prepare and submit appropriate rebuttal evidence.

(d) RECORD. — *The record of evidence taken and papers filed is exclusive for decision and, upon payment of costs, is available to the parties. Where decision rests on official notice of a material fact not appearing in the evidence of record, any party may on timely request show the contrary.*

The "official notice" mentioned relates to the administrative practice of taking facts as shown and true though not in the record. This is done by analogy to judicial notice familiar in court procedure. Where agencies take such notice they must so state on the record or in their decisions and then afford the parties an opportunity to show the contrary.

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SEC. 12. CONSTRUCTION AND EFFECT.—*Nothing in the bill is to diminish constitutional rights or limit or repeal additional requirements of law. Requirements of evidence and procedure are to apply equally to agencies and private persons except as otherwise provided by law. The unconstitutionality of any portion or application of the bill is not to affect other portions or applications. Agencies are granted all authority necessary to comply with the bill. Subsequent legislation is not to modify the bill except as it may do so expressly. The bill would become law three months after its approval except that sections 7 and 8 take effect six months after approval, the requirements of section 11 become effective a year after approval, and no requirement is mandatory as to any agency proceeding initiated prior to the effective date of such requirement.* [p. 29]

V. GENERAL COMMENTS

The bill is designed to operate as a whole and, as previously stated, its provisions are interrelated. At the same time, however, there are certain provisions which touch on subjects long regarded as of the highest importance. On those subjects, such as the separation of examiners from the agencies they serve, there has been a wide divergence of views. The committee has in such cases taken the course which it believes will suffice without being excessive. Moreover, amendatory or supplementary legislation can supply any deficiency which experience discloses in those cases. The committee believes that special note should be made of the following situations:

The exemption of rule making and determining initial applications for licenses from provisions of sections 5 (c), 7 (c), and 8 (a) may require change if, in practice, it develops that they are too broad. Earlier in this report, in commenting upon some of those provisions, the committee has expressed its reasons for the language used and has stated that, where cases present sharply contested issues of fact, agencies should not as a matter of good practice take advantage of the exemptions.

Should the preservation in section 7 (a) of the "conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute" prove to be a loophole for avoidance of the examiner system in any real sense, corrective legislation would be necessary. That provision is not intended to permit agencies to avoid the use of examiners but to preserve special statutory types of hearing officers who contribute something more than examiners could contribute and at the same time assure the parties fair and impartial procedure.

The basic provision respecting evidence in section 7 (c)—requiring that any agency action must be supported by plainly "relevant, reliable, and probative evidence"—will require full compliance by agencies and diligent enforcement by reviewing courts. Should that language prove insufficient to fix and maintain the standards of proof, supplemental legislation will become necessary.

The "substantial evidence" rule set forth in section 10 (e) is exceedingly important. As a matter of language, substantial evidence would seem to be an adequate expression of law. The difficulty comes about in the practice of agencies to rely upon (and of courts to tacitly approve) something less—to rely upon suspicion, surmise, implications, or plainly incredible evidence. It will be the duty of the courts to determine in the final analysis and in the exercise of their independent judgment, whether on the whole record the evidence in a given instance is sufficiently substantial to support a finding, conclusion, or other agency action as a matter of law. In

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HEARINGS

Sec. 7. In hearings which section 4 or 5 requires to be conducted pursuant to this section—

(a) Presiding officers.—There shall preside at the taking of evidence (1) the agency, (2) one or more members of the body which comprises the agency, or (3) one or more examiners appointed as provided in this Act; but nothing in this Act shall be deemed to supersede the conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute. The functions of all presiding officers and of officers participating in decisions in conformity with section 8 shall be conducted in an impartial manner. Any such officer may at any time withdraw if he deems himself disqualified; and, upon the filing in good faith of a timely and sufficient affidavit of personal bias or disqualification of any such officer, the agency shall determine the matter as a part of the record and decision in the case.

(b) Hearing powers.—Officers presiding at hearings shall have authority subject to the published rules of the agency and within its powers, to (1) administer oaths and affirmations, (2) issue subpenas authorized by law, (3) rule upon offers of proof and receive relevant evidence, (4) take or cause depositions to be taken whenever the ends of justice would be served thereby, (5) regulate the course of the hearing, (6) hold conferences for the settlement or simplification of the issues by consent of the parties, (7) dispose of procedural requests or similar matters, (8) make decisions or recommend decisions in conformity with section 8, and (9) take any other action authorized by agency rule consistent with this Act.

(c) Evidence.—Except as statutes otherwise provide, the proponent of a rule or order shall have the burden of proof. Any evidence, oral or documen-

tary, may be received, but every agency shall as a matter of policy provide for the exclusion of immaterial and unduly repetitious evidence and no sanction shall be imposed or rule or order be issued except as supported by relevant, reliable, and probative evidence. Every party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses any agency may, where the interest of any party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(d) Record.—The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, shall constitute the exclusive record for decision in accordance with section 8 and, upon payment of lawfully prescribed costs, shall be made available to the parties. Where any agency decision rests on official notice of a material fact not appearing in the evidence in the record, any party shall on timely request be afforded an opportunity to show the contrary.

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Section 7: This section applies to those cases of statutory hearing which are required by sections 4 and 5 to be conducted pursuant to section 7. Subject to the numerous exceptions contained in sections 4 and 5, they are cases in which an order or rule is to be made upon the basis of the record in a statutory hearing.

Section 7 (a): The subsection is not intended to disturb presently existing statutory provisions which explicitly provide for certain types of hearing officers. Among such are (1) joint hearings before officers of the Federal agencies and persons designated by one or more States, (2) where officers of more than one agency sit, (3) quota allotment cases under the Agricultural Adjustment Act of 1938, (4) marine casualty investigation boards, (5) regis-

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ters of the General Land Office, elections, are not covered. The second sentence of the subsection enables the agency to take official notice of material facts which do not appear in the record, provided the taking of such notice is stated in the record or decision, but in such cases any party affected shall on timely request be afforded an opportunity to show the contrary.

Section 8: This section applies to all hearings held under section 7.

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1.7a (2) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 1980, 79th Cong., 2d Sess. (1946)

ADMINISTRATIVE PROCEDURE ACT

MAY 3, 1946.—Committed to the Committee of the Whole House on the State of the Union and Ordered to be printed

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Mr. WALTER, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 7]

The Committee on the Judiciary, to whom was referred the bill (S. 7) to improve the administration of justice by prescribing fair administrative procedure, having considered the same, report the bill favorably to the House, with an amendment, with the recommendation that, as amended, the bill do pass.

The committee amendment is as follows:

Strike out all of the bill after the enacting clause and insert in lieu thereof the following:

TITLE

SECTION 1. This Act may be cited as the "Administrative Procedure Act".

DEFINITIONS

SEC. 2. As used in this Act—

(a) AGENCY.—"Agency" means each authority (whether or not within or subject to review by another agency) of the Government of the United States other than Congress, the courts, or the governments of the possessions, Territories, or the District of Columbia. Nothing in this Act shall be construed to repeal delegations of authority as provided by law. Except as to the requirements of section 3, there shall be excluded from the operation of this Act (1) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them, (2) courts martial and military commissions, (3) military or naval authority exercised in the field in time of war or in occupied territory, or (4) functions which by law expire on the termination of present hostilities, within any fixed period thereafter, or before July 1, 1947, and the functions conferred by the following statutes: Selective Training and Service Act of 1940; Contract Settlement Act of 1944; Surplus Property Act of 1944.

* * * * * * *

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ADJUDICATION

SEC. 5. In every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing, except to the extent that there is involved (1) any matter subject to a subsequent trial of the law and the facts de novo in any court; (2) the selection or tenure of an officer or employee of the United States other than examiners appointed pursuant to section 11; (3) proceedings in which decisions rest solely on inspections, tests, or elections; (4) the conduct of military, naval, or foreign-affairs functions; (5) cases in which an agency is acting as an agent for a court; and (6) the certification of employee representatives—

(a) NOTICE.—Persons entitled to notice of an agency hearing shall be timely informed of (1) the time, place, and nature thereof; (2) the legal authority and jurisdiction under which the hearing is to be held; and (3) the matters of fact and law asserted. In instances in which private persons are the moving parties, other parties to the proceeding shall give prompt notice of issues controverted in fact or law; and in other instances agencies may by rule require responsive pleading. In fixing the times and places for hearings, due regard shall be had for the convenience and necessity of the parties of their representatives.

(b) PROCEDURE.—The agency shall afford all interested parties opportunity for (1) the submission and consideration of facts, argument, offers of settlement, or proposals of adjustment where time, the nature of the proceeding, and the public interest permit and (2) to the extent that the parties are unable so to determine any controversy by consent, hearing, and decision upon notice and in conformity with sections 7 and 8.

(c) SEPARATION OF FUNCTIONS.—The same officers who preside at the reception of evidence pursuant to section 7 shall make the recommended decision or initial decision required by section 8 except where such officers become unavailable to the agency. Save to the extent required for the disposition of ex parte matters as authorized by law, no such officer shall consult any person or party on any fact in issue unless upon notice and opportunity for all parties to participate; nor shall such officer be responsible to or subject to the supervision or direction of any officer, employee, or agent engaged in the performance of investigative or prosecuting functions for any agency. No officer, employee, or agent engaged in the performance of investigative or prosecuting functions for any agency in any case shall, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 8 except as witness or counsel in public proceedings. This subsection shall not apply in determining applications for initial licenses or to proceedings involving the validity or application of rates, facilities, or practices of public utilities or carriers; nor shall it be applicable in any manner to the agency or any member or members of the body comprising the agency.

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(d) DECLARATORY ORDERS.—The agency is authorized in its sound discretion, with like effect as in the case of other orders, to issue a declaratory order to terminate a controversy or remove uncertainty.

ANCILLARY MATTERS

Sec. 6. Except as otherwise provided in this Act—

(a) APPEARANCE.—Any person compelled to appear in person before any agency or representative thereof shall be accorded the right to be accompanied, represented, and advised by counsel or, if permitted by the agency, by other qualified representative. Every party shall be accorded the right to appear in person or by or with counsel or other duly qualified representative in any agency proceeding. So far as the orderly conduct of public business permits, any interested person may appear before any agency or its responsible officers or employees for the presentation, adjustment, or determination of any issue, request, or controversy in any proceeding (interlocutory, summary, or otherwise) or in connection with any agency function. Every agency shall proceed with reasonable dispatch to conclude any matter presented to it except that due regard shall be had for the convenience and necessity of the parties or their representatives. Nothing herein shall be construed either to grant or to deny any person who is not a lawyer the right to appear for or represent others before any agency or in any agency proceeding.

(b) INVESTIGATIONS.—No process, requirement of a report, inspection, or other investigative act or demand shall be issued, made, or enforced in any manner or for any purpose except as authorized by law. Every person compelled to submit data or evidence shall be entitled to retain or, on payment of lawfully prescribed costs, procure a copy or transcript thereof, except that in a nonpublic investigatory proceeding the witness may for good cause be limited to inspection of the official transcript of his testimony.

(c) SUBPENAS.—Agency subpenas authorized by law shall be issued to any party upon request and, as may be required by rules of procedure, upon a statement or showing of general relevance and reasonable scope of the evidence sought. Upon contest the court shall sustain any such subpena or similar process or demand to the extent that it is found to be in accordance with law and, in any proceeding for enforcement, shall issue an order requiring the appearance of the witness or the production of the evidence or data within a reasonable time under penalty of punishment for contempt in case of contumacious failure to comply.

(d) DENIALS.—Prompt notice shall be given of the denial in whole or in part of any written application, petition, or other request of any interested person made in connection with any agency proceeding. Except in affirming a prior denial or where the denial is self-explanatory, such notice shall be accompanied by a simple statement of procedural or other grounds.

HEARINGS

SEC. 7. In hearings which section 4 or 5 requires to be conducted pursuant to this section—

(a) PRESIDING OFFICERS.—There shall preside at the taking of evidence (1) the agency, (2) one or more members of the body which comprises the agency, or (3) one or more examiners appointed as provided in this Act; but nothing in this Act shall be deemed to supersede the conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute. The functions of all presiding officers and of officers participating in decisions in conformity with section 8 shall be conducted in an impartial manner. Any such officer may at any time withdraw if he deems himself disqualified; and, upon the filing in good faith of a timely and sufficient affidavit of personal bias or disqualification of any such officer, the agency shall determine the matter as a part of the record and decision in the case.

(b) HEARING POWERS.—Officers presiding at hearings shall have authority, subject to the published rules of the agency and within its powers, to (1) administer oaths and affirmations, (2) issue subpenas authorized by law, (3) rule upon offers of proof and receive relevant evidence, (4) take or cause depositions to be taken whenever the ends of justice would be served thereby, (5) regulate the course of the hearing, (6) hold conferences for the settlement or

simplification of the issues by consent of the parties, (7) dispose of procedural requests or similar matters, (8) make decisions or recommend decisions in conformity with section 8, and (9) to take any other action authorized by agency rule consistent with this Act.

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(c) Evidence.—Except as statutes otherwise provide, the proponent of a rule or order shall have the burden of proof. Any oral or documentary evidence may be received, but every agency shall as a matter of policy provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence and no sanction shall be imposed or rule or order be issued except upon consideration of the whole record or such portions thereof as may be cited by any party and as supported by and in accordance with the reliable, probative, and substantial evidence. Every party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses any agency may, where the interest of any party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(d) Record.—The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, shall constitute the exclusive record for decision in accordance with section 8 and, upon payment of lawfully prescribed costs, shall be made available to the parties. Where any agency decision rests on official notice of a material fact not appearing in the evidence in the record, any party shall on timely request be afforded an opportunity to show the contrary.

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SECTION 7. HEARINGS

Section 7 relating to agency hearings applies only where hearings are otherwise required by statute and by section 4 or 5.

As heretofore stated in connection with sections 4 and 5, the bill requires no hearings unless other statutes contain such a requirement in particular cases of either rule making or adjudication and even then section 5 contains numerous functional exceptions. This section 7, therefore, is merely supplementary to section 4 or 5 in the relevant cases. These formal hearing provisions are not in derogation of the settlement provisions of sections 5 and 6 (a), which require that parties be given every opportunity to simplify or settle cases. Hearings are not to be used as indirect burdens or penalties.

SECTION 7 (A). PRESIDING OFFICERS AT HEARINGS

The hearing must be held either by the agency, a member or members of the board which comprises it, one or more examiners, or other officers specially provided for in or designated pursuant to other statutes. All presiding and deciding officers are to operate impartially. They may at any time withdraw if they deem themselves disqualified and, upon the filing of a proper affidavit *of personal bias or disqualification against them, the agency is required to determine the matter as a part of the record and decision in the case.*

The section provides two mutually exclusive methods of hearing—by the agency itself (or one or more of its members) or by subordinate officers. Also recognized as hearing officers are those, including State representatives, specially provided for or named in other statutes. But the reference to other statutory officers would not prevent an agency, such as the head of a department or a board, from utilizing examiners as provided by the bill. On the other hand, statutory provisions authorizing the use of employees or attorneys generally to be presiding officers are superseded. The preservation of the "conduct of specified classes of proceedings by or before boards or other officers specially provided by or designated pursuant to statute" is not a loophole for the avoidance of the examiner system; it is intended to preserve only special types of statutory hearing officers who contribute some special qualifications, as distinguished from examiners otherwise provided in the bill, and at the same time assure the parties fair and impartial procedure.

Those who so preside are subject to the remaining provisions of the bill. They must conduct the hearing in a strictly impartial and considerate manner, rather than as representatives of an investigative or prosecuting authority. They may make sure that all necessary evidence is adduced and keep the hearing orderly and efficient. No examiner may proceed in willful disregard of [p. 34] law. Presiding officers must conduct themselves in accord with the requirements of this bill and with due regard for the rights of all parties as well as the facts, the law, and the need for prompt and orderly dispatch of public business.

The provision for affidavits of bias or personal disqualification requires a decision thereon by the agency in, and as a part of, the case; it thereby becomes subject to administrative and judicial review. That decision might be made upon the affidavit alone, as for example, the protest might be dismissed as insufficient on its face. The agency itself may hear any relevant argument or facts, or it may designate an examiner to do so. The effect which bias or disqualification shown upon the record might have would be determined by the ordinary rules of law and the other provisions of this bill. If it appeared or were discovered late, it would have the effect—where issues of fact or discretion were important and the conduct and demeanor of witnesses relevant in determining them—of rendering the recommended decisions or initial decisions of such officers invalid. This consequence will require agencies and examiners themselves to take care that they do not sit where subject to disqualification.

The term "presiding officers" means those who officially sit and conduct the proceedings for reception of evidence. If more than one so "presides," there may of course be a chairman who also presides in a slightly different but familiar sense as chairman of the presiding body.

SECTION 7 (B). HEARING POWERS OF PRESIDING OFFICERS

Presiding officers, subject to the rules of the procedure adopted by the agency and within its powers, have authority to (1) administer oaths, (2) issue such subpenas as are authorized by law, (3) receive evidence and rule upon offers of proof, (4) take depositions or cause them to be taken, (5) regulate the hearing, (6) hold conferences for the settlement or simplification of issues, (7) dispose of procedural requests, (8) make decisions or recommended decisions under section 8 of the bill, and (9) exercise other authority as provided by agency rule consistent with the remainder of the bill.

The section does not expand the powers of agencies. It assures that the presiding officer or officers will perform a real function rather than serve merely as notaries or policemen. They would have and independently exercise all the powers listed in the section. The agency itself—which must ultimately either decide the case, consider reviewing it, or hear appeals from the examiner's decision—should not in effect conduct hearings from behind the scenes where it cannot know the detailed happenings in the hearing room and does not hear or see the witnesses or private parties.

SECTION 7 (C). EVIDENCE REQUIREMENTS

Except as statutes otherwise provide, the proponent of a rule or order has the burden of proof. While any evidence may be received, as a matter of policy agencies are required to provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence and no sanction may be imposed or rule or order be issued except upon consideration of the whole record or such portions as any party may cite and as supported by and in accordance

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with reliable, probative, and substantial evidence. Any party may present his case or defense by oral or documentary evidence, submit rebuttal evidence, and conduct reasonable cross-examination. However, in the case of rule making or determining applications *for initial licenses, the agency may adopt procedures for the submission of evidence in written form so far as the interest of any party will not be prejudiced thereby.*

That the proponent of a rule or order has the burden of proof means not only that the party initiating the proceeding has the general burden of coming forward with a prima facie case but that other parties, who are proponents of some different result, also for that purpose have a burden to maintain. Similarly the requirement that no sanction be imposed or rule or order be issued except upon evidence of the kind specified means that the proponents of a denial of relief must sustain such denial by that kind of evidence. For example, credible and credited evidence submitted by the applicant for a license may not be ignored except upon the requisite kind and quality of contrary evidence. No agency is authorized to stand mute and arbitrarily disbelieve credible evidence. Except as applicants for a license or other privilege may be required to come forward with a prima facie showing, no agency is entitled to presume that the conduct of any person or status of any enterprise is unlawful or improper. In other words, this section means that every proponent of a rule or order or the denial thereof has the burden of coming forward with sufficient evidence therefor; and in determining applications for licenses or other relief any fact, conduct, or status so shown by credible and credited evidence must be accepted as true except as the contrary has been shown or such evidence has been rebutted or impeached by duly credited evidence or by facts officially noticed and stated.

The second and primary sentence of the section is framed on the premise that, as to the admissibility of evidence, an administrative hearing is to be compared with an equity proceeding in the courts. Thus, the mere admission of evidence is not to be taken as prejudicial error (there being no lay jury to be protected from improper influence) although irrelevant, immaterial, and unduly repetitious evidence is useless and is to be excluded as a matter of efficiency and good practice; and no finding or conclusion may be entered except upon consideration by the agency of the whole record or so much thereof as a party may cite and as supported by and in accordance with evidence which is plainly of the requisite relevance and materiality—that is, "reliable, probative, and substantial evidence." Thus while the exclusionary "rules of evidence" do not apply except as the agency may as a matter of sound practice simplify the hearing and record by excluding improper or unnecessary matter, the accepted standards and principles of probity, reliability, and substantiality of evidence must be applied.

These are standards or principles usually applied tacitly and resting mainly upon common sense which people engaged in the conduct of responsible affairs instinctively understand. But they exist and must be rationally applied. They are to govern in administrative proceedings. These requirements do not preclude the admission of or reliance upon technical reports, surveys, analyses, and summaries where appropriate to the subject matter.

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The first and second sentences of the section therefore mean that, where a party having the burden of proceeding has come forward with a prima facie and substantial case, he will prevail unless his evidence is discredited or rebutted. In any case the agency must decide "in accordance with the evidence." Where there is evidence pro and con, the agency must weigh it and decide in accordance with the preponderance. In short, these provisions require a conscientious and rational judgment on the whole record in accordance with the proofs adduced. The proof must be substantial, as provided in this section and also in section 10 (e) where the term "substantial evidence" is discussed later in this report.

The provision on its face does not confer a right of so-called "unlimited" cross-examination. Presiding officers will have to make the necessary initial determination whether the cross-examination is pressed to unreasonable lengths by a party or whether it is required for the "full and true disclosure of the facts" stated in the provision. Nor is it the intention to eliminate the authority of agencies to confer sound discretion upon presiding officers in the matter of its extent. The test is—as the section states—whether it is required "for a full and true disclosure of the facts." In many rule-making proceedings where the subject matter and evidence are broadly economic or statistical in character and the parties or witnesses numerous, the direct or rebuttal evidence may be of such a nature that cross-examination adds nothing substantial to the record and unnecessarily prolongs the hearings. The right of cross-examination extends, in a proper case, to written evidence submitted pursuant to the last sentence of the section as well as to cases in which oral or documentary evidence is received in open hearing. Even in the latter case, subject to the appropriate safeguards, technical data may as a matter of convenience be reduced to writing and introduced as in courts. Among these are technical statements, reports of surveys, analyses, and summaries. The written evidence provision of the last sentence of the section is designed to cover situations in which, as a matter of general rule or practice, the submission of the whole or substantial portions of the evidence in a case is done in written form. In those situations, however, the provision limits the practice to specified classes of cases and, even then, only where and to the extent that "the interest of any party will not be prejudiced thereby." To the extent that cross-examination is necessary to bring out the truth, the party must have it. An adequate opportunity must also be provided for a party to prepare and submit appropriate rebuttal evidence.

Agencies must comply fully and the courts, pursuant to section 10 of the bill, must enforce all of these requirements diligently.

SECTION 7 (D). RECORD OF HEARINGS

The record of evidence taken and papers filed is exclusive for decision and, upon payment of costs, is available to the parties. Where decision rests on official notice of a material fact not appearing in the evidence of record, any party may on timely request show the contrary.

The "official notice" mentioned relates to the administrative practice of taking facts as shown and true though not in the record. This is done by analogy to "judicial notice" familiar in court procedure. Where agencies take such notice they must so state on the record or in their decisions and then afford the parties

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an opportunity to show the contrary. But such notice may initially be taken only of generally recognized and ordinarily indisputable facts—usually those of a scientific or public nature.

SECTION 8. AGENCY DECISIONS AFTER HEARING

Section 8 applies to cases in which a hearing is required to be conducted pursuant to section 7.

Like section 7, upon which section 8 depends, this section is supplementary to sections 4 and 5 in cases in which agency action is required to be taken after hearing provided by statute and not otherwise expressly excepted. The decision in formal proceedings is exceedingly important, because most criticisms of the administrative process relate in one way or another to the methods whereby agencies decide cases. There are suspicions and good ground for assuming that those who purport to decide cases actually do not, that the submittals of private parties are not fully considered, that the views of agency personnel are emphasized without opportunity for private parties to meet them, and that matters outside the record are often the real grounds of decision.

SECTION 8 (A). DECISIONS BY SUBORDINATES

Where the agency has not presided at the reception of the evidence, the presiding officer (or any other officer) qualified to preside, in cases exempted from section 5 (c)) must make the initial decision unless the agency—by general rule or in a particur case —undertakes to make the initial decision. If the presiding officer makes the initial decision, it becomes the decision of the agency in the absence of an appeal to the agency or review by the agency on its own motion. On such appeal or review by the agency on its own motion. On such appeal or review, the agency has all the powers it would have had in making the initial decision. If the agency makes the initial decision without having presided at the taking of the evidence, whatever officer took the evidence must first make a recommended decision except that, in rule making or determining applications for initial licenses, (1) the agency may instead issue a decision or (2) such intermediate procedure may be wholly omitted in any case in which the agency finds on the record that the execution of its functions imperatively and unavoidably so requires.

These provisions are mandatory but permit agencies to either have their examiners make decisions or, as is now usually the case, recommend decisions. In either case the examiner system is necessary because agencies cannot themselves hear all cases. Where they do not do so some device must be used to bridge the gap between the officials who hear and those who decide cases. The provision that on agency review of initial examiners' decisions it has all the powers it would have had in making the initial decision itself does not mean that initial examiners' decisions or recommended decisions are without effect. They become a part of the record and are of consequence, for example, to the extent that material facts in any case depend on the determination of credibility of witnesses as shown by their demeanor or conduct at the hearing. In a broad sense the agencies' reviewing powers are to be compared with that of courts under section 10 (e).

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HEARINGS

Sec. 7. In hearings which section 4 or 5 requires to be conducted pursuant to this section—

(a) PRESIDING OFFICERS.—There shall preside at the taking of evidence (1) the agency, (2) one or more members of the body which comprises the agency, or (3) one or more examiners appointed as provided in this Act; but nothing in this Act shall be deemed to supersede the conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute. The functions of all presiding officers and of officers participating in decisions in conformity with section 8 shall be conducted in an impartial manner. Any such officer may at any time

withdraw if he deems himself disqualified; and, upon the filing in good faith of a timely and sufficient affidavit of personal bias or disqualification of any such officer, the agency shall determine the matter as a part of the record and decision in the case.

(b) Hearing powers.—Officers presiding at hearings shall have authority, subject to the published rules of the agency and within its powers, to (1) administer oaths and affirmations, (2) issue subpenas authorized by law, (3) rule upon offers of proof and receive evidence, (4) take or cause depositions to be taken whenever the ends of justice would be served thereby, (5) regulate the course of the hearing, (6) hold conferences for the settlement or simplification of the issues by consent of the parties, (7) dispose of procedural requests or similar matters, (8) make decisions or recommend decisions in conformity with section 8, and (9) take any other action authorized by agency rule consistent with this Act.

(c) Evidence.—Except as statutes otherwise provide, the proponent of a rule or order shall have the burden of proof. Any [evidence] oral or documentary *evidence*[15] may be received, but every agency shall as a matter of policy provide for the exclusion of *irrelevant,*[16] immaterial, [and] *or* unduly repetitious evidence and no sanction shall be imposed or rule or order be issued except *upon consideration of the whole record or such portions thereof as may be cited by any party and*[17] as supported by *and in accordance with the* [relevant] reliable, [and] probative, *and substantial* evidence.[18] Every party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses any agency may, where the interest of any party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(d) Record.—The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, shall constitute the exclusive record for decision in accordance with section 8 and, upon payment of lawfully prescribed costs, shall be made available to the parties. Where any agency decision rests on official notice of a material fact not appearing in the evidence in the record, any party shall on timely request be afforded an opportunity to show the contrary.

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[15] The prior form involved an unnecessary circumlocution of language.

[16] The word "relevant" has been stricken from the latter part of this sentence and the word "irrelevant" has been inserted at this point where it more appropriately belongs, to achieve the same purpose.

[17] That the whole of the relevant record must be considered is the rule laid down in section 10 (e) on judicial review, but some hypercritical mind might contend that the omission to specify such consideration at the agency stage of proceedings was intentional and meant that the agency is not required to consider the whole record.

[18] The insertion of the word "substantial" is made for the same reason as the insertion explained in note 17. Obviously the agency will proceed in accordance with the evidence which it finds reliable, probative, and substantial—there is no reason why the bill should not say so.

1.7a (3) CONGRESSIONAL RECORD, VOL. 92 (1946)

1.7a (3) (a) March 12: Debated and passed Senate, pp. 2151, 2155–2159, 2162, 2165, 2167

Mr. McCARRAN.

* * * * *

Now let me point out some of the essential respects in which the pending bill differs from the Walter-Logan bill. The bill now before the Senate differentiates the several types of rules. It requires no agency hearings in connection with either regulations or adjudications unless statutes already do so in particular cases, thereby preserving rights of individual trials de novo. Where statutory hearings are otherwise provided, this bill fills in some of the essential requirements; and it provides for a special class of semi-independent subordinate hearing officers.

* * * * *

I cannot emphasize too strongly that the bill now before the Senate is not a specification of the details of administrative procedure. Neither is it a codification of administrative law. It represents, instead, an outline of minimum basic essentials, framed out of long consideration and in the light of the comprehensive studies I have previously mentioned.

To state it simply, this bill is designed to afford parties affected by administrative powers a means of knowing what their rights are, and how they may be protected. At the same time, administrators are provided with a simple course to follow in making administrative determinations. The jurisdiction of the courts is clearly stated. The bill thus provides for public information, administrative operation, and judicial review.

The substance of what the bill does may be summarized under four headings:

First. It provides that agencies must issue as rules certain specified information as to their organization and procedure, and also make available other materials of administrative law.

Second. It states the essentials of the several forms of administrative proceedings and the limitations on administrative powers.

Third. It provides in more detail the requirements for administrative hearings and decisions in cases in which statutes require such hearings.

Fourth. It sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong.

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Section 4 concerns rule making. The introductory clause exempts from all of the requirements of section 4 any rule making, so far as there are involved military, naval, or foreign affairs functions, or matters relating to agency management or personnel, or to public property, loans, grants, benefits, or contracts.

Mr. President, I wish the Senate would give close consideration to what I am about to discuss, because it is all important.

Subsection (a) of section 4 concerns notice. It provides that general notice of proposed rule making must be published in the Federal Register and must include the time, place, and nature of the proceedings, a reference to the authority under which such proceedings are held, and the terms, substance, or issues involved. However, except where notice and hearing is required by some other statute, the subsection does not apply to rules other than those of substance, or where the agency for good cause finds, and incorporates the finding and reasons therefor in the published rule, that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.

Subsection (b) of section 4 concerns procedures. This subsection provides that after such notice as required by the preceding subsection, the agency must afford interested persons an opportunity to participate in the rulemaking, at least to the extent of submitting written data, views, or argument. This subsection also provides that after consideration of such presentations, the agency must incorporate in any rules adopted a concise general statement of their basis and purpose. However, where other statutes require rules to be made after hearing, the requirements of sections 7 and 8, which relate to public hearings and decisions thereon, apply in place of the provisions of this subsection.

Subsection (c) of section 4 refers to effective dates. The required publication or service of any substantive rule must, under this provision, be made not less than 30 days prior to the effective date of such rule, except as otherwise provided by the agency for good cause found and published, or, in the case of rules recognizing exemption or relieving restriction, interpretative rules, and statements of policy.

Subsection (d) of section 4 concerns petitions, and provides that every agency shall accord any interested person the right to petition for the issuance, amendment, or repeal of a rule.

Section 5 of the bill concerns adjudications. The initial provision of this section makes it clear that subsequent provisions of the section apply only where the case is otherwise required by statute to be determined upon an agency hearing, except that, even in that case, the following classes of operations are expressly not affected: First, cases subject to trial de novo in court; second, selection or tenure of public officers other than examiners; third, decisions resting on inspections, tests, or elections; fourth, military, naval, and foreign affairs functions; fifth, cases in which an agency is acting for a court; and, sixth, the certification of employee representatives.

Subsection (a) of section 5 refers to notice. Under this subsection, persons entitled to notice of an agency hearing are to be duly and timely informed of the time, place, and nature of the hearing, the legal authority and jurisdiction under which it is to be held, and the matters of fact and law asserted. Where private persons are the moving parties, respondents must give prompt notice of issues controverted in law or fact; and in other cases the agency may require responsive pleading. In fixing the times and places for hearings the agency must give due regard to the convenience and necessity of the parties.

Subsection (b) of section 5 concerns procedure. Under this subsection the agency is required first to afford parties an opportunity for the settlement or adjustment of issues, where time, the nature of the proceeding, and the public interest permit; and then requires that such opportunity for settlement or adjustment be followed, to the extent that issues are not so settled or adjusted, by hearing and decision under sections 7 and 8.

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Section 7 concerns hearings and applies only where hearings are required by section 4 or 5.

Subsection (a) of section 7 provides that the hearing must be held either by the agency, a member or members of the board which comprises it, one or more examiners, or other officers specially provided for in other statutes or designated by other statutes. All presiding and deciding officers are to operate impartially. They may at any time withdraw if they deem themselves disqualified; and, upon the filing of a proper affidavit of personal bias or disqualification against them, the agency is required to determine the matter as a part of the record and decision in the case.

Subsection (b) of section 7 concerns hearing powers. It provides that presiding officers, subject to the rules of procedure adopted by the agency and within its powers, have authority as follows: First, to administer oaths; second, to issue such subpenas as are authorized by law; third, to receive evidence and rule upon offers of proof; fourth, to take depositions or cause depositions to be taken; fifth, to regulate the hearing; sixth, to hold conferences for the settlement or simplification of the issue; seventh, to dispose of procedural requests; eighth, to make decisions or recommended decisions under section 8 of the bill; and, ninth, to exercise other authority as provided by agency rule consistent with the remainder of the bill.

Subsection (c) of section 7 relates to evidence. It provides that except as statutes otherwise provide, the proponent of a rule or order has the burden of proof. While any evidence may be received, as a matter of policy agencies are required to provide for the exclusion of irrelevant and unduly repetitious evidence, and no sanction may be imposed, or rule or order issued, except as supported by relevant, reliable, and probative evidence. Any party may present his case or defense by oral or documentary evidence, may submit rebuttal evidence, and may conduct reasonable cross-examination. However, in the case of rule making or determining applications for initial licenses, the agency may adopt procedures for the submission of evidence in written form so far as the interest of any party will not be prejudiced thereby.

Mr. AUSTIN. Mr. President, at that point I wish the Senator from Nevada would yield for a question.

Mr. McCARRAN. I gladly yield to the Senator from Vermont.

Mr. AUSTIN. Did the committee intentionally choose the language "except as supported by relevant, reliable, and probative evidence" in order to avoid the rule of scintilla of proof? This phrase is very significant, as I see it. On review, for example, the case, in order to carry through as decided by the agency, would have to be supported by relevant, reliable, and probative evidence. That is, in my opinion, a very important forward step in judicial procedure, to say nothing about administrative procedure. For my part I am glad to see it in the bill.

Mr. McCARRAN. Let me say to the Senator from Vermont that in the preparation of this bill many obstacles were encountered. Some of us insisted that the testimony must be relevant, material, and competent, and that nothing else should be taken. However, representatives of agencies came before us and presented their views, saying that such a rule would curtail their operations, and that they ought to be given greater latitude. They said to us, "We are not lawyers." We are acting in a quasi-judicial capacity. We ought to be able to go outside and get hearsay testimony, if you please. We might be able to indulge in theory." So rather than curtail the agencies, we sought an intermediate ground which we thought would be protective of the rights of individuals, and at the same time would not handicap the agencies. So we said to them, "You may go outside and get what would be secondary evidence, or hearsay; you may perhaps even go into the realm of conjecture; but when you write your decision it must be based upon probative evidence and nothing else. If in the formation of your decision you consider other than probative evidence, your decision will be subject to being set aside by a court of review."

In other words, we did not wish to destroy the administrative agencies or prescribe the methods under which they have been operating. Some of us know that in committees of the Senate we very frequently hear evidence which we know is hearsay. I doubt very much if any hearing is ever conducted in which, to some extent, hearsay is not admitted. But we believed, and we now believe, that reasonable men can sift the grain from the chaff. Then we laid down the rule that the administrative agencies must not make a finding which impinges upon an individual unless there is behind such finding probative evidence to sustain it. That is what we have worked out in this bill. I have given the explanation at some length in answer to the Senator from Vermont.

Mr. FERGUSON. Mr. President, will the Senator yield?

Mr. McCARRAN. I yield.

Mr. FERGUSON. Would the Senator, then, say that the judgment or decision of the agency must be based upon stronger proof than a scintilla of evidence?

Mr. McCARRAN. Very much stronger.

Mr. FERGUSON. The old rule which applied in the courts, particularly on certiorari, was that if there was any evidence to sustain the verdict or judgment, it should be sustained. The courts have many times so held. The Senator would say, would he not, that something more than "any evidence" is required to sustain such a decision.

Mr. McCARRAN. The answer is in the affirmative. We say that the evidence must be substantial probative evidence.

Mr. FERGUSON. So we are changing the rule which has been applied in the past that any evidence, or a scintilla of evidence, as it is sometimes defined, is sufficient to sustain a verdict or judgment.

Mr. McCARRAN. We tried as best we could to establish a guide for administrative groups so that they would apply the rule in such a way that there would be substantial probative evidence behind their findings, and so that they could say, "We are not afraid to have our findings reviewed by a court."

Mr. GEORGE. Mr. President, will the Senator yield?

Mr. McCARRAN. I yield.

Mr. GEORGE. The courts have many times held that if there is any evidence to sustain the finding of an administrative board under the statute, the courts have no power to intervene. If this bill should become a law would that rule, as heretofore construed by the courts, remain in effect?

Mr. McCARRAN. The courts have given various constructions. The

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courts, in reviewing an order, are governed by the provisions of section 10 (e), which states the substantial-evidence rule. In other words, in some instances the courts have held that there must be substantial evidence. We are saying that there must be probative evidence of a substantial nature, and that even though the commission or bureau may take hearsay evidence in its hearings, it must have some probative evidence to sustain its finding.

Mr. GEORGE. The point I wish to raise is that some of the acts of Congress, particularly those enacted in recent years, have led the courts to hold—and they so hold—that if there be any evidence to sustain the finding of a board or agency, the court has no power to interfere with it.

Mr. McCARRAN. I would put it in this way—

Mr. GEORGE. Would the enactment of this bill require some substantial or probative evidence to support such a finding?

Mr. McCARRAN. Yes.

Mr. GEORGE. Take the labor relations cases. Senators are familiar with them. The circuit courts have frequently complained against what the Labor Relations Board did, but have said, "We are powerless to interfere with it." Would this bill change that rule, if the court were of the opinion that there was no probative evidence?

Mr. McCARRAN. Yes; it would change that rule.

Mr. GEORGE. I am pleased to hear it.

Mr. McCARRAN. I thank the Senator.

Subsection (d) of section 7 provides that the record of evidence taken and papers filed is exclusive for decision, and, upon payment of costs, is available to the parties. Where decision rests on official notice of a material fact not appearing in the evidence of record, any party may on timely request show the contrary.

Section 8 relates to decisions, and applies to cases in which a hearing is required to be conducted pursuant to section 7.

Subsection (a) of section 8 relates to action by subordinates. It provides that where the agency has not presided at the reception of the evidence, the presiding officer, or any other officer qualified to preside, in cases exempted from subsection (c) of section 5, must make the initial decision unless the agency, by general rule or in a particular case, undertakes to make the initial decision. If the presiding officer makes the initial decision, it becomes the decision of the agency in the absence of an appeal to the agency or review by the agency on its own motion. On such appeal or review, the agency has all the powers it would have had in making the initial decision. If the agency makes the initial decision without having presided at the taking of the evidence, whatever officer took the evidence must first make a recommended decision, except that, in rule making or determining applications for initial licenses, the agency may instead issue a tentative decision or any of its responsible officers may recommend a decision, or such intermediate procedure may be wholly omitted in any case in which the agency finds on the record that the execution of its functions imperatively and unavoidably requires.

Subsection (b) of section 8 concerns submittals and decisions. It provides that prior to each recommended or other decision or review, the parties must be given an opportunity to submit for the full consideration of deciding officers, first, proposed findings and conclusions, or exceptions to recommended decisions or other decisions being appealed or reviewed; and, second, supporting reasons for such findings, conclusions, or exceptions. All recommended or other decisions become a part of the record and must include findings and conclusions, as well as the basis therefor, upon all the material issues of fact, law, or discretion presented by the record, besides including the appropriate agency action or denial.

Section 9 concerns sanctions and powers, and relates to the exercise of any power or authority by an agency.

Unlike sections 7 and 8, section 9 applies in all relevant cases, regardless of whether the agency is required by statute to proceed upon hearing or in any special manner. Section 9 also applies to any power or authority that an agency may assume to exercise.

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That completes the synopsis of the bill.

Mr. President, as I have pointed out before, this bill is designed to operate as a whole, and its provisions are closely interrelated. At the same time, it should be pointed out that there are certain provisions which touch upon subjects long regarded as of the highest importance. On some of these subjects, such as the separation of examiners from the agencies they serve, there has been a wide divergence of views. The committee has, in such cases, taken the course which it believes will suffice, without being excessive. Amendatory or supplementary legislation can supply any deficiency which experience discloses in such cases. The committee believes that special note should be made of these situations:

The exemption of rule making and determining applications for licenses, from provisions of sections 5 (c), 7 (c), and 8 (a) may require change if, in practice, it develops that they are too broad. The committee believes it has followed sound discretion in selection of the language used, and it is the feeling of the committee that, where cases present sharply contested issues of fact, agencies should not as a matter of good practice take advantage of the exemptions.

The committee has considered the possibility that the preservation in section 7 (a) of the "conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute" might prove to be a loophole for avoidance of the examiner system. If experience should prove this true in any real sense, corrective legislation would be or might be necessary. Therefore, the committee desires that Government agencies should be put on notice that the provision in question is not intended to permit agencies to avoid the use of examiners, but only to preserve special statutory types of hearing officers who contribute something more than examiners could contribute, and at the same time to assure the parties fair and impartial procedure.

The basic provision respecting evidence, in section 7 (c)—the provision requiring that any agency action must be supported by plainly "relevant, reliable, and probative evidence"—will require full compliance by agencies, and diligent enforcement by reviewing courts, and so forth. Should the language prove insufficient to fix and maintain the standards of proof, supplemental legislation will become necessary. That is another matter which, at the outset of legislation such as this must depend upon the spirit in which the agencies attempt to comply fully with the law. The committee anticipates nothing less than full compliance and adequate enforcement; and, with such compliance and enforcement, the committee believes that the language in question will be adequate.

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Section 7 contains provisions relating to decisions for the initial submission of briefs, proposed findings and conclusions, and oral argument for consideration in preparing an initial decision, or where subordinate officers preside, an intermediate report, the details of such report or decision, provisions for administrative review, the consideration of cases, the findings and opinions and the service thereof upon all the parties.

The provisions of these two sections on fair hearings and findings or decisions should serve to meet most of the heated criticisms heretofore directed against administrative agencies in the conduct of hearings. Most well-run agencies have already provided for such procedures.

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HEARINGS

SEC. 7. In hearings which section 4 or 5 requires to be conducted pursuant to this section—

(a) Presiding officers: There shall preside at the taking of evidence (1) the agency (2) one or more members of the body which comprises the agency, or (3) one or more examiners appointed as provided in this act; but nothing in this act shall be deemed to supersede the conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute. The functions of all presiding officers and of officers participating in decisions in conformity with section 8 shall be conducted in an impartial manner. Any such officer may at any time withdraw if he deems himself disqualified; and, upon the filing in good faith of a timely and sufficient affidavit of personal bias or disqualification of any such officer, the agency shall determine the matter as a part of the record and decision in the case.

(b) Hearing powers: Officers presiding at hearings shall have authority, subject to the published rules of the agency and within its powers to (1) administer oaths and affirmations, (2) issue subpenas authorized by law (3) rule upon offers of proof and receive relevant evidence, (4) take or cause depositions to be taken whenever the ends of justice would be served thereby, (5) regulate the course of the hearing, (6) hold conferences for the settlement or simplification of the issues by consent of the parties, (7) dispose of procedural requests or similar matters, (8) make decisions or recommend decisions in conformity with section 8 and (9) take any other action authorized by agency rule consistent with this act.

(c) Evidence: Except as statutes otherwise provide, the proponent of a rule or order shall have the burden of proof. Any evidence, oral or documentary, may be received but every agency shall as a matter of policy provide for the exclusion of immaterial and unduly repetitious evidence and no sanction shall be imposed or rule or order be issued except as supported by relevant, reliable, and probative evidence. Every party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses any agency may, where the interest of any party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(d) Record: The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, shall constitute the exclusive record for decision in accordance with section 8 and, upon payment of lawfully prescribed costs, shall be made available to the parties. Where any agency decision rests on official notice of a material fact not appearing in the evidence in the record, any party shall on timely request be afforded an opportunity to show the contrary.

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The amendment was agreed to.

The PRESIDING OFFICER. The question is on the engrossment and the third reading of the bill.

The bill (S. 7) was ordered to be engrossed for a third reading, read the third time, and passed.

[p. 2167]

1.7a (3) (b) May 24: Debated, amended and passed House, pp. 5645, 5649, 5652–5653, 5655, 5665, 5668

ADMINISTRATIVE PROCEDURE ACT

Mr. SABATH. Mr. Speaker, I call up House Resolution 615 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

Resolved, That upon the adoption of this resolution it shall be in order to move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the act (S. 7) to improve the administration of justice by prescribing fair administrative procedure. That after general debate, which shall be confined to the act and continue not to exceed 2 hours, to be equally divided and controlled by the chairman and the ranking minority member of the Committee on the Judiciary, the act shall be read for amendment under the 5-minute rule. At the conclusion of the consideration of the act for amendment, the Committee shall rise and report the act to the House with such amendments as may have been adopted and the previous question shall be considered as ordered on the act and amendments thereto to final passage without intervening motion except one motion to recommit.

TO IMPROVE ADMINISTRATIVE PROCEDURE

Mr. SABATH. Mr. Speaker, later on I shall yield 30 minutes to the gentleman from Michigan [Mr. MICHENER].

Mr. Speaker, House Resolution 615 makes in order the consideration of Senate 7 as amended by the Committee on the Judiciary. The bill aims to improve the administration of justice by prescribing fair administrative procedure. The rule is an open rule, and provides for 2 hours of general debate.

Mr. Speaker, I hope this is only the beginning of legislation to improve the administration of justice and that it will bring about real justice to all those who are obliged to face our courts.

PUBLICITY VALUABLE CONTRIBUTION

There is general agreement that the present bill has not only eliminated the objections previously made but has achieved a substantial contribution in its publicity requirements; and that it has arrived at an equitable and helpful differentiation of the legislative or rule-making powers and the quasi-judicial powers frequently lodged in the same agency.

What the bill does, in substance, may be summarized under four headings:

First. It provides that agencies must issue as rules certain specified information as to their organization and procedure, and also make available other materials of administrative law.

Second. It states the essentials of the several forms of administrative proceedings and the general limitations on administrative powers.

Third. It provides in more detail the requirements for administrative hearings and decisions in cases in which statutes require such hearings.

Fourth. It sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong.

[p. 5645]

But this bill does more than merely analyze the administrative process and lay down the forms of procedure for each. It really deals with three separate subjects: First, public information; second, administrative operation; and third, judicial review.

The first operative section of the bill is basic and requires agencies to issue certain information which is essential to inform the public about the substance and the procedure of administrative law. It requires that agencies state their organizational set-ups, promulgate statements respecting their procedures, and make available as regulations the substantive and interpretative rules which they have framed for the guidance of the public.

Sections 4, 5, 6, 8, 9, and 11 deal with administrative operations. Section 4 relates to the legislative functions of administrative agencies and provides that where Congress has not required hearings, with some exceptions, the agency shall give notice of the making of proposed regulations and afford interested parties an opportunity for the informal submission and consideration of their views or requests. Section 5 deals with administrative adjudications of particular cases where Congress has required adjudications to be made upon a hearing. Sections 7, 8, and 11 spell out the details of hearing and decision procedures in all cases in which, by other legislation, Congress has required an agency hearing. Section 9 states certain limitations upon the penalties or relief which agencies may impose or confer in any case. Section 6 deals with the investigative powers and other incidental matters of importance.

In the all-important field of judicial review section 10 is a complete statement of the subject. It prescribes briefly when there may be judicial review and how far the courts may go in examining into a given case.

* * * * *

IV. DETAILED PROVISIONS

In taking up the specific provisions of the bill as reported to the House, I will not attempt to restate all of the detail which appears in the committee report at pages 18 to 48. I shall try, however, to emphasize those things which are of paramount importance and at the same time state how the provisions of the bill as a whole are intended to operate.

[p. 5649]

HEARINGS, SECTION 7

It will be recalled that section 4—relating to rule making—and section 5—relating to the determination of particular cases—refer to situations in which Congress has by some other statute required an agency to act upon a hearing. Accordingly sections 7 and 8, which I am about to discuss, state the requisites of statutory agency hearings and decisions.

PRESIDING OFFICERS, SECTION 7 (A)

The first subsection of section 7 requires an agency to hold hearings itself, or through a member or members of the board which comprises it, or by one or more examiners qualified as provided in section 11 of the bill, or through other officers specially provided for or designated pursuant to the authority contained in other statutes. Whoever presides must do so impartially. They may withdraw if they deem themselves disqualified or, if an affidavit of personal bias or disqualification is filed against them, the agency must determine the issue as a part of the record and decision in the case.

This provision authorizes agencies, if they do not wish to hear cases themselves, to delegate the hearing function to the named types of presiding officers. It does not mean, however, that agencies are authorized—whether pursuant to the express authority of other statutes or not—to avoid the examiner system—set up in this bill and hereafter discussed— by assigning general employees or attorneys to hear cases individually or as boards. In short, unless the agency or its members or some specially qualified statutory officer hears the case, an examiner qualified under section 11 of this bill must do so.

Of particular importance in this subsection is the requirement that any presiding officer must act impartially rather than as a prosecutor. These provisions mean that presiding officers will be required to conduct themselves in the manner in which people think they should—that is, as judges and not as the representatives of factions or special interests.

HEARING POWERS, SECTION 7 (B)

Subsection (b) of section 7 lists the commonly accepted kinds of powers which it is generally conceded that officers who preside at hearings ought to have. These include administering oaths, issuing authorized subpenas, receiving or excluding evidence, taking depositions, generally regulating the hearing, holding informal conferences with the parties for the settlement or simplification of issues, disposing of procedural requests such as those for adjournment, and the like. In exercising these powers, of course, presiding officers will be bound by relevant legal limitations.

EVIDENCE, SECTION 7 (C)

Subsection (c) of section 7 is one of the more important provisions of the bill. In its final report the Attorney General's Committee on Administrative Procedure stated that—pages 70-71:

> Although administrative agencies may be freed from observance of strict common-law rules of evidence for jury trials, it is erroneous to suppose that agencies do not, as a result, observe some rules of evidence. * * * Abuses in admitting remote hearsay and irrelevant or unreliable evidence there surely have been. * * * That strict adherence to standards of relevance and probative value should be observed needs no underscoring. A diffuse record dissipates the energies of the parties and the deciding authorities and distracts attention from the issues. Careless admission of evidence for what it is worth—a practice not infrequent among trial examiners—swells the record beyond its necessary limits.

Section 7 (c) of this bill provides that the proponent of a rule or order has the burden of proof except as statutes otherwise provide. It authorizes agencies to receive any evidence, although as a matter of policy they are required to provide for the exclusion of irrelevant, immaterial, or unduly repetitious matter. Thus, the mere fact that such matter is in the record would not of itself be reversible error. The principal provision of the subsection provides that no sanction may be imposed or rule or order be issued except upon consideration of the whole record or such portions as any party may cite and as supported by and in accordance with reliable, probative, and substantial evidence. The parties are authorized to present documentary, oral, and rebuttal evidence and to conduct reasonable cross-examination. In rule making or determining applications for initial licenses agencies may adopt procedures for the submission of the evidence in written form, so far as the interest of any party will not be prejudiced thereby.

The requirement that agencies may act only upon relevant, probative, and substantial evidence means that the accepted standards of proof, as distinguished from the mere admissibility of evidence, are to govern in administrative proceedings as they do in courts of law and equity. The same provision contains two other limitations—first, that the agency must examine and consider the whole of the evidence relevant to any issue and, secondly, that it must decide in accordance with the evidence.

Under these provisions the function of an administrative agency is clearly not to decide arbitrarily or to act contrary to the evidence or upon surmise or suspicion or untenable inference. Mere uncorroborated hearsay or rumor does not constitute substantial evidence—see *Edison Co.* v. *Labor Board* (305 U. S. 197, 230). Under this provision agencies are not authorized to decide in accordance with preconceived ideas or merely to sustain or vindicate prior administrative action, but they must enter upon a bona fide consideration of the record with a view to reaching a just decision upon the whole of it.

RECORD, SECTION 7 (D)

The final subsection of section 7 provides that the record of the evidence taken and the papers filed is exclusive for purposes of decision. It also provides that, where a decision rests in whole or part on official notice of a material fact not appearing in the record, any party must on timely request be given an adequate opportunity to show the true facts.

Both of these provisions are important. The exclusiveness of the record precludes deciding officers from basing their judgments as to the facts upon matters which are not in the record. The provision respecting official notice is essential in order to prevent miscarriages of justice through mistake or by unwarranted expansion of the idea of judicial notice.

[p. 5653]

EXAMINERS, SECTION 11

One of the most controversial proposals in the field of administrative law relates to the status and independence of examiners who hear cases where agencies themselves or members of boards cannot do so. I have heretofore referred to this problem in my discussion of section 8 respecting decisions. Both sections 7 and 8 authorize the use of examiners. Section 11, which I am about to discuss, provides for their selection, tenure, and compensation.

* * * * *

CONSTRUCTION AND EFFECT, SECTION 12

The final section of the bill provides that nothing in it is to diminish constitutional or other legal rights, that requirements of evidence and procedure are to apply equally to agencies and private persons, that the unconstitutionality of any portion or application of the bill shall be subject to the usual saving provision, and that subsequent legislation is not to be deemed to modify the bill except as it may do so expressly.

The final sentence provides that the bill shall become law 3 months after its approval, except that sections 7 and 8 respecting statutory hearings and decisions shall not take effect until 6 months after its approval, the requirements of section 11 respecting the selection of examiners are not to become effective for a year, and no requirement of the bill is mandatory as to any agency proceeding initiated prior to the effective date of such requirement.

The staggered effective date provision has been thought necessary in order to give administrative agencies every opportunity to prepare fully.

V. CONCLUSION

This measure is the culmination of long and earnest consideration. It responds to a widespread, deep-seated, and insistent public demand for some attention to the problem of administrative justice and administrative operations. It has been drafted with the greatest of care and upon fulsome consideration of views from every side. It is not, of course, the final word, but it is a good beginning.

[p. 5655]

"HEARINGS

"SEC. 7. In hearings which section 4 or 5 requires to be conducted pursuant to this section—

"(a) Presiding officers: There shall preside at the taking of evidence (1) the agency, (2) one or more members of the body which comprises the agency, or (3) one or more examiners appointed as provided in this act; but nothing in this act shall be deemed to supersede the conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute. The functions of all presiding officers and of officers participating in decisions in conformity with section 8 shall be conducted in an impartial manner. Any such officer may at any time withdraw if he deems himself disqualified; and, upon the filing in good faith of a timely and sufficient affidavit of personal bias or disqualification of any such officer, the agency shall determine the matter as a part of the record and decision in the case.

"(b) Hearing powers: Officers presiding at hearings shall have authority, subject to the published rules of the agency and within its powers, to (1) administer oaths and affirmations, (2) issue subpenas authorized by law, (3) rule upon offers of proof and receive relevant evidence, (4) take or cause depositions to be taken whenever the ends of justice would be served thereby, (5) regulate the course of the hearing, (6) hold conferences for the settlement or simplification of the issues by consent of the parties, (7) dispose of procedural requests or similar matters, (8) make decisions or recommend decisions in conformity with section 8, and (9) take any other action authorized by agency rule consistent with this act.

"(c) Evidence: Except as statutes otherwise provide, the proponent of a rule or order shall have the burden of proof. Any oral or documentary evidence may be received, but every agency shall as a matter of policy provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence and no sanction shall be imposed or rule or order be issued except upon consideration of the whole record or such portions thereof as may be cited by any party and as supported by and in accordance with the reliable, probative, and substantial evidence. Every party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses any agency may, where the interest of any party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

"(b) Record: The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, shall constitute the exclusive record for decision in accordance with section 8 and, upon payment of lawfully prescribed costs, shall be made available to the parties. Where any agency decision rests on official notice of a material fact not appearing in the evidence in the record, any party shall on timely request be afforded an opportunity to show the contrary.

[p. 5665]

The CHAIRMAN. Under the rule, the Committee rises.

Accordingly the Committee rose; and the Speaker having resumed the chair, Mr. SMITH of Virginia, Chairman of the Committee of the Whole House on the State of the Union, reported that that Committee having had under consideration the bill (S. 7) to improve the administration of justice by prescribing fair administrative procedure, pursuant to House Resolution 615, he reported the bill back to the House with an amendment adopted by the Committee of the Whole.

The SPEAKER. Under the rule, the previous question is ordered.

The question is on the amendment.

The amendment was agreed to.

The SPEAKER. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time and was read the third time.

The SPEAKER. The question is on the passage of the bill.

The bill was passed.

A motion to reconsider was laid on the table.

[p. 5668]

1.7a (3) (c) May 27: Senate concurs in House amendment, p. 5790

Mr. McCARRAN. Mr. President, some weeks ago the Senate passed Senate bill No. 7, which is known as the administrative procedure bill.

The Senator from Maine will recall that the bill passed the Senate, after a careful discussion, without a dissenting vote. Let me say that the bill has been under study and consideration for nearly 10 years. For about 2 years, while the present chairman of the Judiciary Committee and other members of that committee have had the matter in hand, a very careful and meticulous study has been made of the whole subject. The House did not in any substantial particular amend the Senate bill. The only thing which the House did was to clarify the bill in respect to a few of its provisions. I can best illustrate that by a brief statement from the Attorney General as to what the House did. Without quoting him at length, the Attorney General said that he approved the amendments which had been made by the House which were merely explanatory in nature.

For that reason, Mr. President, I move that the Senate concur in the House amendment. [p. 5790]

1.7b ADMINISTRATIVE PROCEDURE IN HEARINGS AMENDMENTS

September 6, 1966, P.L. 89–554, §556, 80 Stat. 386

§556. Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision

(a) This section applies, according to the provisions thereof, to hearings required by section 553 or 554 of this title to be conducted in accordance with this section.

(b) There shall preside at the taking of evidence—

(1) the agency;

(2) one or more members of the body which comprises the agency; or

(3) one or more hearing examiners appointed under section 3105 of this title.

This subchapter does not supersede the conduct of specified classes of proceedings, in whole or in part, by or before boards or other employees specially provided for by or designated under statute. The functions of presiding employees and of employees participating in decisions in accordance with section 557 of this title shall be conducted in an impartial manner. A presiding or participating employee may at any time disqualify himself. On the filing in good faith of a timely and sufficient affidavit of personal bias or other disqualification of a presiding or participating employee, the agency shall determine the matter as a part of the record and decision in the case.

(c) Subject to published rules of the agency and within its powers, employees presiding at hearings may—

(1) administer oaths and affirmations;

(2) issue subpenas authorized by law;

(3) rule on offers of proof and receive relevant evidence;

(4) take depositions or have depositions taken when the ends of justice would be served;

(5) regulate the course of the hearing;

(6) hold conferences for the settlement or simplification of the issues by consent of the parties;

(7) dispose of procedural requests or similar matters;

(8) make or recommend decisions in accordance with section 557 of this title; and

(9) take other action authorized by agency rule consistent with this subchapter.

(d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or

[p. 386]

benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(e) The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 of this title and, on payment of lawfully prescribed costs, shall be made available to the parties. When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.

[p. 387]

1.7b (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 901, 89th Cong., 1st Sess. (1965)

TITLE 5, UNITED STATES CODE, "GOVERNMENT ORGANIZATION AND EMPLOYEES"

AUGUST 31, 1965.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WILLIS, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 10104]

The Committee on the Judiciary, to whom was referred the bill (H.R. 10104) to enact Title 5, United States Code, "Government Organization and Employees," codifying the general and permanent laws relating to the organization of the Government of the United States and to its civilian officers and employees, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PRELIMINARY STATEMENT

Purpose.—The purpose of this bill is to restate in comprehensive form, without substantive change, the statutes in effect before July 1, 1965, that relate to Government employees, the organization and powers of Federal agencies generally, and administrative procedure, and to enact title 5 of the United States Code. In the revised title 5, simple language has been substituted for awkward and obsolete terms, and superseded, executed, and obsolete statutes have been eliminated. This bill is a part of the program of the Committee on the Judiciary of the House of Representatives to enact into law all fifty titles of the United States Code.

[p. 1]

SECTION 556

Derivation: United States Code	Revised Statutes and Statutes at Large
5 U.S.C. 1006	June 11, 1946, ch 324, § 7, 60 Stat. 241.

In subsection (b), the words "hearing examiners" are substituted for "examiners" in paragraph (3) for clarity. The prohibition in the second sentence is restated in positive form and the words "This subchapter does not" are substituted for "but nothing in this chapter shall be deemed to." The words "employee" and "employees" are substituted for "officer" and "officers" in view of the definition of "employee" in section 2105. The sentence

"A presiding or participating employee may at any time disqualify himself." is substituted for the words "Any such officer may at any time withdraw if he deems himself disqualified."

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

[p. 13]

1.7b (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 1380, 89th Cong., 2d Sess. (1966)

TITLE 5, UNITED STATES CODE, "GOVERNMENT ORGANIZATION AND EMPLOYEES"

JULY 21, 1966.—Ordered to be printed

Mr. ERVIN, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 10104]

The Committee on the Judiciary, to which was referred the bill (H.R. 10104), to enact title 5, United States Code, "Government Organization and Employees," codifying the general and permanent laws relating to the organization of the Government of the United States and to its civilian officers and employees, having considered the same, reports favorably thereon, with amendments, and recommends that the bill, H.R. 10104, as amended, do pass.

[p. 1]

SECTION 556

Derivation: United States Code	Revised Statutes and Statutes at Large
5 U.S.C. 1006	June 11, 1946, ch. 324, § 7, 60 Stat. 241.

In subsection (b), the words "hearing examiners" are substituted for "examiners" in paragraph (3) for clarity. The prohibition in the second sentence is restated in positive form and the words "This subchapter does not" are substituted for "but nothing in this chapter shall be deemed to." The words "employee" and "employees" are substituted for "officer" and "officers" in view of the definition of "employee" in section 2105. The sentence "A presiding or participating employee may at any time disqualify himself." is substituted for the words "Any such officer may at any time withdraw if he deems himself disqualified."

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report. [p. 30]

1.7b (3) CONGRESSIONAL RECORD

1.7b (3) (a) VOL. 111 (1965), Sept. 7: Considered and passed House, p. 22954

[No Relevant Discussion on Pertinent Section]

1.7b (3) (b) VOL. 112 (1966), July 25: Amended and passed Senate, p. 17010

[No Relevant Discussion on Pertinent Section]

1.7b (3) (c) VOL. 112 (1966), Aug. 11: House concurs in Senate amendments, p. 19077

[No Relevant Discussion on Pertinent Section]

1.8 RECORD ON REVIEW AND ENFORCEMENT OF AGENCY ORDERS, AS AMENDED, 28 U.S.C. §2112 (1966)

[Referred to in 7 U.S.C. §135b(d), 21 U.S.C. §§346a (i) (2) (3), 348(g) (2), 15 U.S.C. §1474(b) (1)]

1.8a UNIFORM REVIEW, RECORDS AND ENFORCEMENT ORDERS AMENDMENTS

August 28, 1958, P.L. 85-791, §2, 72 Stat. 941

AN ACT

To authorize the abbreviation of the record on the review or enforcement of orders of administrative agencies by the courts of appeals and the review or enforcement of such orders on the original papers and to make uniform the law relating to the record on review or enforcement of such orders, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the analysis of chapter 133 of title 28 of the United States Code, immediately preceding section 2101 of such title, is amended by inserting at the end thereof the following additional item:

"2112. Record on review and enforcement of agency orders."

"Sec. 2. Chapter 133 of title 28 of the United States Code is amended by inserting at the end of such chapter immediately following section 2111 an additional section, as follows:

"§2112. Record on review and enforcement of agency orders

"(a) The several courts of appeals shall have power to adopt, with the approval of the Judicial Conference of the United States, rules, which, so far as practicable, shall be uniform in all such courts prescribing the time and manner of filing and the contents of the record in all proceedings instituted in the courts of appeals to enjoin, set aside, suspend, modify, or otherwise review or enforce orders of administrative agencies, boards, commissions, and officers, to the extent that the applicable statute does not specifically prescribe such time or manner of filing or contents of the record. Such rules may authorize the agency, board, commission, or officer to file in the court a certified list of the materials comprising the record and retain and hold for the court all such materials and transmit the same or any part thereof to the court, when and as required by it, at any time prior to the final determination of the proceeding, and such filing of such certified list of the materials comprising the record and such subsequent transmittal of any such materials when and as required shall be deemed full compliance with any provision of law requiring the filing of the record in the court. The record in such proceedings shall be certified and filed in or held for and transmitted to the court of appeals by the agency, board, commission, or officer concerned within the time and in the manner prescribed by such rules. If proceedings have been instituted in two or more courts of appeals with respect to the same order the agency, board, commission, or officer concerned shall file the record in that one of such courts in which a proceeding with respect to such order was first instituted. The other courts in which such proceedings are pending shall thereupon transfer them to the court of appeals in which the record has been filed. For the convenience of the parties in the interest of justice such court may thereafter transfer all the proceedings with respect to such order to any other court of appeals.

"(b) The record to be filed in the court of appeals in such a proceeding shall consist of the order sought to be reviewed, or enforced, the findings or report upon which it is based, and the pleadings, evidence, and proceedings before the agency, board, commission, or officer concerned, or such portions thereof (1) as the said rules of the court of appeals may require to be included therein, or (2) as the agency, board, commission, or officer concerned, the petitioner for review or respondent in enforcement, as the case may be, and any intervenor in the court proceeding by written stipulation filed with the agency, board, commission, or officer concerned or in the court in any such proceeding may consistently with the rules of such court designate to be

[p. 941]

included therein, or (3) as the court upon motion of a party or, after a prehearing conference, upon its own motion may by order in any such proceeding designate to be included therein. Such a stipulation or order may provide in an appropriate case that no record need be filed in the court of appeals. If, however, the correctness of a finding of fact by the agency, board, commission, or officer is in question all of the evidence before the agency, board, commission, or officer shall be included in the record except such as the agency, board, commission, or officer concerned, the petitioner for review or respondent in enforcement, as the case may be, and any intervenor in the court proceeding by written stipulation filed with the agency, board, commission, or officer concerned or in the court agree to omit as wholly immaterial to the questioned finding. If there is omitted from the record any portion of the proceedings before the agency, board, commission, or officer which the court subsequently determines to be proper for it to consider to enable it to review or enforce the order in question the court may direct that such additional portion of the proceedings be filed as a supplement to the record. The agency, board, commission, or officer concerned may, at its option and without regard to the foregoing provisions of this subsection, and if so requested by the petitioner for review or respondent in enforcement shall, file in the court the entire record of the proceedings before it without abbreviation.

"(c) The agency, board, commission, or officer concerned may transmit to the court of appeals the original papers comprising the whole or any part of the record or any supplemental record, otherwise true copies of such papers certified by an authorized officer or deputy of the agency, board, commission, or officer concerned shall be transmitted. Any original papers thus transmitted to the court of appeals shall be returned to the agency, board, commission, or officer concerned upon the final determination of the review or enforcement proceeding. Pending such final determination any such papers may be returned by the court temporarily to the custody of the agency, board, commission, or officer concerned if needed for the transaction of the public business. Certified copies of any papers included in the record or any supplemental record may also be returned to the agency, board, commission, or officer concerned upon the final determination of review or enforcement proceedings.

"(d) The provisions of this section are not applicable to proceedings to review decisions of the Tax Court of the United States or to proceedings to review or enforce those orders of administrative agencies, boards, commissions, or officers which are by law reviewable or enforceable by the district courts." [p. 942]

1.8a (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 842, 85th Cong., 1st Sess. (1957)

AUTHORIZING ABBREVIATED RECORDS IN REVIEWING ADMINISTRATIVE AGENCY PROCEEDINGS

JULY 23, 1957.—Ordered to be printed

Mr. WILLIS, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 6788]

The Committee on the Judiciary, to whom was referred the bill (H.R. 6788) to authorize the abbreviation of the record on the review or enforcement of orders of administrative agencies by the courts of appeals and the review or enforcement of such orders on the original papers and to make uniform the law relating to the record on review or enforcement of such orders, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill do pass.

The amendments are as follows:

* * * * * * *

[p. 1]

EXPLANATION OF AMENDMENTS

***Amendment No. 1.*—Several of the Federal agencies and the American Bar Association propose that the bill be amended to require the adoption of *uniform* rules. While uniformity is highly desirable, there will be special conditions in particular circuits which will not obtain generally. This amendment seeks substantial uniformity by requiring the approval of the Judicial Conference to rules promulgated by the various courts of appeals while at the same time permitting individual courts to make special provision required by peculiar local conditions.**

The latter part of this amendment makes it clear that the rules to be adopted by the courts of appeals may cover the matters of time of filing, manner of filing, and contents of the record *to the full extent* that such matters or any of them are not specifically covered by applicable statutes.

***Amendment No. 2.*—Subsection (a) of new section 2112 has been expanded in accordance with suggestions made at the hearing on May 17, 1956, to provide that the rules of court may authorize the agency concerned, to file a certified list of the materials comprising the record and retain the actual papers in its physical custody to be transmitted to the court only when and if required**

by the court in its consideration of the case. This procedure has been recently tried in several of the courts and found feasible. In carrying out this provision the instant amendment was inserted to provide that the filing of a certified list of materials will be deemed full compliance with any provision of law requiring the filing of the record.

Amendment No. 3.—This amendment was made in the interest of precision to implement the provisions of amendment No. 2.

Amendments Nos. 4 and 5.—The bill, as introduced, provided that if proceedings have been instituted in two or more courts with respect to the same order, the agency would be required to file the record in that court which in its judgment would be most convenient to the parties, and the other courts were then to transfer their proceedings to it. This was intended to provide statutory authority for the procedure developed by the courts in this situation. See *Columbia Oil and Gas Co.* v. *Securities and Exchange Commission* (3d Cir. 1943, 134 F. 2d 265); *L. J. Marquis & Co.* v. *Securities & Exch. Com.* (2 Cir. 1943, 134 F. 2d 335); *L. J. Marquis & Co.* v. *Securities & Exchange Com.* (3 Cir. 1943, 134 F. 2d 822). This provision would have provided a general rule applicable to all agency review cases. The use of the phrase "in its judgment" was intended to make clear that the choice of forum in such a case was in the discretion of the agency and was not to be reviewable [p. 4] except for clear abuse of discretion. However, the American Bar Association and several of the agencies found fault with the provision and recommended that the court of appeals—and not a Federal agency—in which the first proceeding was instituted, should have exclusive jurisdiction of all proceedings involving the same order with authority to transfer all the proceedings to another court of appeals if that would best serve the convenience of the parties. The committee has adopted this suggestion, and the instant amendments carry out this recommendation.

Amendment No. 6.—It was suggested that additional portions of the record ought to be ordered filed when the court thinks it "proper." It need not be shown to be "necessary" before the court may do so. Accordingly, this amendment was adopted to carry out the suggestion.

Amendment No. 7.—Following the introduction of the bill, it developed that as a result of recent rule changes, no court of appeals now requires the entire record to be printed. This limitation rendered the provision affected by this amendment unnecessary.

Amendment No. 8.—The American Bar Association suggested that the petitioner for review and the respondent in enforcement proceedings should have the option to require the entire proceeding to be filed in the court. Since subsection (b) of new section 2112 includes a provision giving the agencies the right, at their option, to file the entire record in the courts, it was deemed proper that petitioners and respondents, at their option, should also have the same right, and this amendment so provides.

Amendment No. 9.—This amendment makes a technical change in the bill.

Amendment No. 10.—This amendment was adopted to make clear that the bill is not intended to apply to the review of decisions of the Tax Court, which is not an administrative agency, or to the review of agency orders which are by law reviewable by the district courts and not, in the first instance, by the several courts of appeals.

Amendments Nos. 11 and 12.—These amendments remove any possible ambiguity as to the right of the Federal Trade Commission to modify or revoke an order under review prior to the filing of the record. At the same time, the amendments do not interfere with the basic scheme of the bill to make clear in all cases that jurisdiction attaches in the court of appeals for the purpose of making interlocutory and procedural orders from the time of filing of the petition for review.

Amendments Nos. 13, 14, 15, 16, and 17.—These are clarifying amendments, and were suggested by the Department of Agriculture.

Amendment No. 18.—This amendment was adopted at the suggestion of the Securities and Exchange Commission to make clear that that Commission has concurrent jurisdiction with the court of appeals to modify, amend, or revoke its own order between the time the petition for review is filed and the time the record is filed. This permits the Commission to carry out the provisions of the Securities and Exchange Act of 1934, the Public Utility Holding Company Act of 1935, the Investment Company Act of 1940 and the Investment Advisers Act of 1940. It was pointed out at the hearing that, in these cases, there is no advantage to be gained by conferring exclusive jurisdiction on the court of appeals before the record is filed in that court. In fact, in some instances, such a procedure might have the effect of depriving a party of the right of a rehearing before the Commis-
[p. 5]
sion and might be construed to deny the Commission the power

to stay its own orders after the filing of a petition for review.

Amendments Nos. 19 and 20.—These amendments correct typographical errors.

Amendment No. 21.—See explanation of amendment No. 18 above.

Amendment No. 22.—This amendment corrects typographical error.

Amendment No. 23.—This is a clarifying amendment.

Amendments Nos. 24, 25, and 26.—These amendments are needed to indicate that the definition of "commission" includes both the Federal Maritime Board and the Department of Commerce, as set out in section 905 (e) of the Merchant Marine Act of 1936, as amended.

Amendment No. 27.—This is a clarifying amendment.

Amendment No. 28.—This is a technical amendment.

Amendments Nos. 29, 30, and 31 are procedural amendments.

Amendments Nos. 32 and 33.—These are clarifying amendments suggested by the Department of Agriculture.

Amendments Nos. 34 and 35.—See explanation of amendment No. 18 above.

Amendments Nos. 36 and 37.—These amendments give the courts of appeals jurisdiction upon the filing of the notice of appeal.

Amendment No. 38.—Section 32 of the bill as introduced is deleted by this amendment. The Federal Coal Mine Safety Board of Review pointed out that the procedure upon review of the orders of that Board is not analogous to other review proceedings covered by the bill. The Board's proceedings are purely advisory between parties before the Board and the Board itself is not a party to the review proceeding. After the committee had decided to eliminate these provisions from section 32 of the bill, it further decided, at the suggestion of the Department of Health, Education, and Welfare, to add a provision to amplify section 207 (b) of the act of September 23, 1950, to bring that law in harmony with the other provisions of the bill affecting the Department of Health, Education, and Welfare. This provision now forms section 32.

Amendments Nos. 39, 40, and 41.—These amendments correct typographical errors.

PURPOSE

The purpose of the bill is to permit the several courts of appeals to adopt rules authorizing the abbreviation of the transcript and other parts of the record made before Federal administrative agencies when the orders of those agencies are to be reviewed by the courts of appeals.

In many instances much of the record made before such agencies is not relevant to the questions actually raised on appeal. This legislation, in permitting an abbreviated record to be transmitted, should result in a substantial saving of time and money without interfering with any of the appellate rights which persons now have under existing law.

BACKGROUND

In 1953 the Judicial Conference of the United States referred to its Committee on Revision of the Laws a proposal that existing statutes be amended so as to permit administrative agencies whose orders are to be reviewed by a court of appeals to send to the court an abbreviated record where the whole record is not necessary. The proposal also provided for the authorization of the use of the [p. 6] original papers in appropriate cases in lieu of a transcript, the papers to be returned to the administrative agency upon the completion of the review proceedings. The Judicial Conference committee concluded that the proposal had substantial merit.

An examination of the Federal statutes authorizing judicial review of orders of administrative agencies by that committee disclosed that many of them now specifically require a transcript of the *entire* record to be filed by the agency in the court of appeals. It was thought that these requirements should be eliminated except in those instances where for some other reason it is necessary to file the entire record.

This objective could, perhaps, have been accomplished by a general statute repealing all inconsistent provisions of the various acts providing for judicial review of agency action. But this would have left the law in confusion as to what specific provisions would have been thus repealed by implication. The Judicial Conference committee became satisfied that in order to deal comprehensively with the problem it would be necessary to amend many of the existing statutes.

In addition it seemed advisable to that committee to add a new section 2112 to title 28 of the United States Code which would confer rulemaking power in this field upon the courts of appeals with the approval of the Judicial Conference. Such a statute should, the committee thought, be modeled upon section 6 of the Hobbs Act of December 29, 1950 (5 U.S.C. 1036), which provides for uniform rules promulgated by the courts of appeals with the approval of the Judicial Conference.

The Committee on Revision of the Laws of the Judicial Conference accordingly prepared a tentative draft of such an amendatory statute and submitted it to all the judges of the courts of appeals and to all the agencies involved for their study and suggestions.

It received a large number of constructive suggestions which it embodied in the revision of the bill which was introduced in the 84th Congress as H.R. 6682, and which was the subject of a hearing before Subcommittee No. 3 of the House Committee on the Judiciary on May 17, 1956. Thereafter a further document was compiled made up of hearings, Government agency reports, and other comments (hearings, Serial No. 25, House Committee on the Judiciary, 84th Cong.), and was made available to all interested organizations so that their views could be obtained on the proposed legislation.

When the legislation (H.R. 6788) was introduced in this Congress, further hearings were held. The Judiciary Committee has considered the suggestions and feels that the instant bill, as amended, will make a valuable contribution to the law of appellate administrative procedures.

The bill has been approved in principle by the American Bar Association. It incorporates the recommendation of the President's Conference on Administrative Procedure in this field. It has the approval of the Judicial Conference of the United States.

STATEMENT AND ANALYSIS OF BILL

The instant bill would add to title 28 of the United States Code a new section 2112 entitled "Record on review and enforcement of agency orders." The section includes enforcement as well as review proceedings in the courts of appeals.

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Subsection (a) of new section 2112 as set out in section 2 of the bill gives the courts of appeals power to adopt, with the approval of the Judicial Conference, rules prescribing the time and manner of filing and the contents of the record in all such proceedings instituted in those courts to review orders of Federal administrative agencies, unless present law affecting those agencies specifically provides a procedure on the subject. The general power granted by section 2112 (a), however, will render separate statutory provisions unnecessary in the future.

The section also provides that the rules of court may authorize the Federal administrative agency concerned to file a certified list of the materials comprising the record and retain the actual papers in its physical custody to be transmitted to the court only when and if required by the court in its consideration of the case. This has been a procedure which has been recently tried in several of the appellate courts and has been found quite feasible, saving both time and money.

As the result of a suggestion by the Securities and Exchange Commission subsection (a) also includes a provision providing that if review proceedings have been instituted in two or more courts with respect to the same order, the Federal administrative agency involved shall file the record in that court in which a proceeding was first instituted. The courts in which other proceedings are pending thereupon will transfer their proceedings to the court of appeals in which the record has been filed. In the interest of justice and for the convenience of the parties, such court may thereafter transfer the proceedings to another court of appeals.

Subsection (b) of proposed section 2112 provides for the abbreviation of the record by the inclusion only of such material as the rules of the court may require, or as the parties, including parties permitted to intervene by the court, may stipulate, or as the court may designate by order. The stipulation or order may provide in an appropriate case, such as a petition for a consent degree enforcing a National Labor Relations Board order, that no record at all be filed. There are in the courts of appeals many cases in which the National Labor Relations Board petitions the court to enter an enforcement decree which has been consented to by the parties concerned. The Board under present law must spend the time and public money required to send the court a complete transcript of the record before the latter can enter the decree requested. Subsection (b) will permit dispensing with the filing of the record in such a case, and a decree may be entered upon the petition and consenting answer or stipulation.

The provisions of subsection (b) will also enable the parties to abbreviate the record by eliminating all material not relevant to the actual questions raised on review, with consequent saving of time and expense. Provision is made, however, that additional portions of the record may be ordered by the court if found to be needed.

If the correctness of a finding of fact is in issue, subsection (b) requires all the evidence to be included in the record except such part as the parties, by stipulation, agree to omit as wholly immaterial to the questioned finding. This provision will enable the court to perform its duty in cases under section 10 (e) of the Administrative Procedure Act to "review the whole record or such portions thereof as may be cited by any party."

Several of the Federal agencies advised the committee that in some instances it would not only delay proceedings but it would be [p. 8] more costly to abbreviate the record than it would be to send it in its entirety to the court of appeals. The subsection therefore contains a provision giving Federal agencies the right, at their option, to file the entire record instead of an abbreviated record.

The American Bar Association suggested, among other things that the petitioner for review and the respondent in enforcement proceedings, should also have the right, at their option, to require the filing of the entire record. In accordance with this recommendation, the bill provides for the filing of the entire record of the proceedings upon such request.

Subsection (c) of new section 2112 as set out in section 2 of the bill authorizes the transmittal of certified copies instead of the original papers. A number of agencies pointed out that many of their records are public records which are required to be kept in their offices open to public inspection. It was also pointed out that in many instances an agency must retain the original papers for use in connection with a related case which is before it but which is not on review. The subsection therefore contains a provision authorizing the transmittal of the original papers at the option of the agency. It also provides that this situation may pertain to a part, as well as to the whole of, the record so that an agency may transmit some original papers and certified copies of others. All original papers and certified copies are to be returned to the agency at the conclusion of the case.

The bill is not intended to apply to the review of decisions of the Tax Court, which is not an administrative agency, or to the review of such agency orders as are by law reviewable by the district courts, such as exclusion and deportation orders. The Department of Justice has suggested that this be made explicit in the proposed legislation. Therefore, subsection (d) has been added to the proposed section 2112 to clarify the congressional intent.

Many of the statutes providing for the enforcement or review of agency orders provide that the courts of appeals acquire jurisdiction upon the filing of the petition for review. Many others provide, however, that jurisdiction is not acquired by the courts until the filing of the transcript of the record. It was pointed out at the hearing that this latter provision is illogical and unwise, illogical since it places it within the power of the Federal agency to delay the acquisition of full jurisdiction by the court, and unwise since it raises a serious question as to the extent of the court's power to make orders relating to the filing of the record or other preliminary orders between the time of filing the petition for review and the time the record is actually filed. Accordingly, to take care of this situation, the language of the bill adopts the pattern of the Hobbs Act (5 U.S.C. 1036) relating to the review of orders of certain Federal agencies, and proposes to amend the various statutes to provide in all cases that the reviewing court shall acquire jurisdiction upon the filing of the petition on review.

At the hearings the committee's attention was called to the fact that the Federal Trade Commission act, the Clayton Act, the Packers and Stockyards Act, the National Labor Relations Act, the Federal Power Act and the National Gas Act provide that an agency acting under and pursuant to them may modify or set aside its order after a petition for review has been filed and up to the time of the filing of the record. Giving exclusive jurisdiction to the courts upon the filing of the petition, as the instant bill, as intro-

[p. 9]

duced, provides, could work undue hardship. The bill was therefore amended to provide that although jurisdiction shall be immediately acquired by the court upon the filing of a petition for review, such jurisdiction will be concurrent and shall become exclusive only upon the filing of the record.

Sections 3 to 33 contain provisions which make changes to present law. For the most part those changes are to conform the present provisions of law to section 2 of the bill and are explained in another part of this report under "Explanation of amendments." The agencies, boards, commissions or offices whose orders are to be reviewable under the statutes proposed to be amended by sections 3 to 34 of the bill are the following:

* * * * * * *

[p. 10]

the words "under the provisions of this act," should be inserted after the words "in part". The word "find" on page 17, line 5, should be amended to read "finding."

However, legislation on this subject may not be necessary at this time because the entire matter can be handled adequately by court rules. For example, a number of the courts (Court of Appeals 2d, 3d, 4th, 5th, 10th, and the District of Columbia Circuit) have promulgated rules to facilitate the filing of agency records for review. There could readily be opportunity for further experimentation, which is possible under the statutes as they now stand, but in any event the present degree of flexibility in such matters should be preserved.

FEDERAL POWER COMMISSION,
By JEROME K. KUYKENDALL, *Chairman*

TITLE 28. UNITED STATES CODE

CHAPTER 133. REVIEW—MISCELLANEOUS PROVISIONS

* * * * * * *

2112. Record on review and enforcement of agency orders.

* * * * * * *

§ *2112. Record on review and enforcement of agency orders.*

(a) The several courts of appeals shall have power to adopt, with the approval of the Judicial Conference of the United States, rules, which so far as practicable shall be uniform in all such courts prescribing the time and manner of filing and the contents of the record in all proceedings instituted in the courts of appeals to enjoin, set aside, suspend, modify, or otherwise review or enforce orders of administrative agencies, boards, commissions, and officers, to the extent that the applicable statute does not specifically prescribe such time or manner of filing or contents of the record. Such rules may authorize the agency, board, commission, or officer to file in the court a certified list of the materials comprising the record and retain and hold for the court all such materials and transmit the same or any part thereof to the court, when and as required by it, at any time prior to the final determination of the proceeding, and such filing of such certified list of the materials comprising the record and such subsequent transmittal of any such materials when and as required shall be deemed full compliance with any provision of law requiring the filing of the record in the court. The record in such proceedings shall be certified and filed in or held for and transmitted to the court of appeals by the agency, board, commission, or officer concerned within the time and in the manner prescribed by such rules. If proceedings have been instituted in two or more courts of appeals with respect to the same order the agency, board, commission or officer concerned shall file the record in that one of such courts in which a proceeding with respect to such order was first instituted. The other courts

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in which such proceedings are pending shall thereupon transfer them to the court of appeals in which the record has been filed. For the convenience of the parties in the interest of justice such court may thereafter transfer all the proceedings with respect to such order to any other court of appeals.

(b) The record to be filed in the court of appeals in such a proceeding shall consist of the order sought to be reviewed or enforced, the findings or report upon which it is based, and the pleadings, evidence, and proceedings before the agency, board, commission, or officer concerned, or such portions thereof (1) as the said rules of the court of appeals may require to be included therein, or (2) as the agency, board, commission, or officer concerned, the petitioner for review or respondent in enforcement, as the case may be, and any intervenor in the court proceeding by written stipulation filed with the agency, board, commission, or officer concerned or in the court in any such proceeding may consistently with the rules of such court designate to be included therein, or (3) as the court upon motion of a party or, after a prehearing conference, upon its own motion may by order in any such proceeding designate to be included therein. Such a stipulation or order may provide in an appropriate case that no record need be filed in the court of appeals. If, however, the correctness of a finding of fact by the agency, board, commission, or officer is in question all of the evidence before the agency, board, commission, or officer shall be included in the record except such as the agency, board, commission, or officer concerned, the petitioner for review or respondent in enforcement, as the case may be, and any intervenor in the court proceeding by written stipulation filed with the agency, board, commission, or officer concerned or in the court agree to omit as wholly immaterial to the questioned finding. If there is omitted from the record any portion of the proceedings before the agency, board, commission, or officer which the court subsequently determines to be proper for it to consider to enable it to review or enforce the order in question the court may direct that such additional portion of the proceedings be filed as a supplement to the record. The agency, board, commission, or officer concerned may, at its option and without regard to the foregoing provisions of this subsection, and if so requested by the petitioner for review or respondent in enforcement shall, file in the court the entire record of the proceedings before it without abbreviation.

(c) The agency, board, commission, or officer concerned may transmit to the court of appeals the original papers comprising the whole or any part of the record or any supplemental record, otherwise true copies of such papers certified by an authorized officer or deputy of the agency, board, commission, or officer concerned shall be transmitted. Any original papers thus transmitted to the court of appeals shall be returned to the agency, board, commission, or officer concerned upon the final determination of the review or

enforcement proceeding. Pending such final determination any such papers may be returned by the court temporarily to the custody of the agency, board, commission, or officer concerned if needed for the transaction of the public business. Certified copies of any papers included in the record or any supplemental record may also be returned to the agency, board, commission, or officer concerned upon the final determination of review or enforcement proceedings.

(d) The provisions of this section are not applicable to proceedings to review decisions of the Tax Court of the United States or to proceedings to review or enforce those orders of administrative agencies, boards, commissions, or officers which are by law reviewable or enforceable by the district court.

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1.8a (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 2129, 85th Cong., 2d Sess. (1958)

AUTHORIZING ABBREVIATED RECORDS IN REVIEWING ADMINISTRATIVE AGENCY PROCEEDINGS

AUGUST 4, 1958.—Ordered to be printed

Mr. EASTLAND, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 6788]

The Committee on the Judiciary, to which was referred the bill (H.R. 6788) to authorize the abbreviation of the record on the review or enforcement of orders of administrative agencies by the courts of appeals and the review or enforcement of such orders on the original papers and to make uniform the law relating to the record on review or enforcement of such orders, and for other purposes, having considered the same, reports favorably thereon, without amendment, and recommends that the bill do pass.

PURPOSE

The purpose of the proposed legislation is to save time and expense by permitting the several courts of appeals to adopt rules authorizing the abbreviation of the transcript and other parts of the record made before Federal administrative agencies when the orders of those agencies are to be reviewed by the courts of appeals. If review proceedings have been instituted in two or more courts with respect to the same order, the bill would require the Federal administrative agency involved to file the record in that court in which the proceeding was first instituted, but in the interest of justice and for the convenience of the parties, such court may thereafter transfer the proceedings to another court of appeals.

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STATEMENT

1. ORIGIN AND PRIOR CONSIDERATION

This proposal emanates from the Judicial Conference of the United States. It was submitted to the Congress after substantial consideration by the Committee on Revision of the Laws of the Judicial Conference and the Judicial Conference itself. After submission, it was the subject of a hearing before a subcommittee of the House Committee on the Judiciary on May 17, 1956, and subjected to agency comments. It was thereafter revised and reintroduced and again subjected to review by the administrative agencies. Following this, the Judiciary Committee after adopting several amendments, reported the bill to the House of Representatives, which later approved it.

The bill has been approved in principle by the American Bar Association, and it incorporates a recommendation of the President's Conference on Administrative Procedure. It likewise carries the approval of the Judicial Conference of the United States.

2. DISCUSSION AND SUMMARY

Most of the present statutes which provide for judicial review or enforcement by the courts of appeals of the orders of administrative agencies require that a transcript of the entire record of the proceedings before the agency be prepared by the agency and physically filed with the court. Such a requirement frequently operates to delay court proceedings and to impose upon the agency large and unnecessary expenditures of money and effort. In many types of cases the agency record involves persons other than the petitioner for review. The record may, therefore, be unnecessarily voluminous and much of it irrelevant to the review.

The object of the instant legislation is to eliminate the filing of the entire record except in those instances where it is required for an adequate determination or where the abbreviation of the record would prove more costly than the transmission of the entire record. This objective could have been accomplished by a general statute repealing all inconsistent provisions of the various acts providing for judicial review of agency action. Such a course, however, would have left a residuum of doubt as to whether specific provisions would have been repealed by implication. This legislation avoids that difficulty by direct amendment of the many existing statutes providing for judicial review of administrative determinations and orders.

The bill is not intended to apply to the review of decisions of the Tax Court, which is not an administrative agency within the contemplation of this measure, or to the review of such agency orders as are by law reviewable by the district courts, such as exclusion and deportation orders.

Many of the statutes providing for the enforcement or review of agency orders provide that the courts of appeals acquire jurisdiction upon the filing of the petition for review. Many others provide, however, that jurisdiction is not acquired by the courts until the filing of the transcript of the record. This latter provision has sometimes proved both illogical and unwise—illogical, since it places authority within the Federal agency to delay the acquisition of full jurisdiction by a Federal appellate court; and unwise, since it raises a serious question concerning the extent of the court's

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authority to make orders relating to the filing of the record or other preliminary orders between the time of filing the petition for review and the time when the record is actually filed. Accordingly, this legislation proposes to amend various statutes to provide that in all cases the reviewing court shall acquire jurisdiction upon the filing of a petition for review. However, the bill further provides that although jurisdiction shall be immediately acquired by the court upon the filing of a petition for review, the existing jurisdiction of agencies, pending filing of the record, is preserved and until such filing the jurisdiction shall be concurrent and shall become exclusive in the appellate court only upon the filing of the record. This provision was added in order to make clear that up to the filing of the record or transcript, an agency may retain jurisdiction in order to permit that agency to entertain motions for additional processes before the administrative agency, such as the modification or setting aside of an order.

This legislation accomplishes its objective of permitting the filing of abbreviated records by adding a new section, section 2112, to title 28 of the United States Code, and amending the several statutes relating to appeals from administrative agencies to bring them into conformity with the provisions of this new section of title 28. The bill seeks to accomplish its purposes in the following ways:

(1) By giving the courts of appeals, with the approval of the Judicial Conference, authority to adopt rules on the subject, which are to be so far as practicable uniform in all courts.

(2) By providing for the abbreviation of the record to include only those materials which are relevant to the issues involved as determined by the rules or special orders of the court or by stipulation of the parties.

(3) By providing in appropriate cases which can be disposed of on the pleadings, such as consent decrees, that no record at all need be filed.

(4) By permitting the entire record to be filed in those cases where the parties find it will be less expensive and time consuming to do so than to select and copy portions of it for filing. The selection of the relevant portions of the record to be printed in the petitioner's appendix can sometimes better be done at the brief-writing stage.

(5) By providing that the courts may permit an agency to file in court merely a list of the materials in the record while retaining in its custody the materials themselves until any such materials are actually needed and sent for by the court.

(6) By authorizing the agency, if it finds it better to do so, to transmit original papers, rather than copies, as the record on review. These are, of course, to be returned to the agency upon the termination of the proceeding, or earlier if needed.

The bill would further accomplish its objectives by amending the various statutes now providing for the review and enforcement of agency orders so as to bring about uniformity in their provisions by—

(7) Providing that the record shall be filed in each case as provided in the new section 2112 of title 28;

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(8) Providing that the jurisdiction of the court of appeals shall attach in all cases upon the filing of the petition for review or enforcement, while preserving the concurrent jurisdiction of the agency, in appropriate cases, until the record is filed; and

(9) Providing that in all cases it shall be the duty of the clerk of the court to transmit to the agency a copy of the petition for review which has been filed with the court.

In addition, the bill meets the problem which is presented when petitions by different aggrieved parties to review the same agency order are filed in different circuits. It does so by providing that the court of appeals in which the first petition is filed shall have exclusive jurisdiction of all the petitions but with power to transfer them all to another court of appeals if the convenience of the parties and the interests of justice so require. At present the agency, by selecting the court in which it files the record, determines which court shall have jurisdiction.

CONCLUSION

With the advent of an increasing number of bureaus and agencies within the Federal Government, the Congress has seen fit to authorize judicial review of the orders of such agencies and bureaus in order to afford maximum protection to the interests of the Government and the individual or corporate litigant. In many cases this review function has been placed upon the Federal courts of appeals, thereby increasing the workload of that part of the Federal court system. Part of that workload involves the perusal of records filed in connection with such appeals. These records are frequently voluminous and are not edited, so as to encompass only information relevant to the points at issue. The reduction of such a record to its pertinent parts, as proposed here, should in most cases serve as an aid to the expedition of appeals from orders of administrative agencies. Thus, adoption of this measure is expected to facilitate the work of the Federal appellate courts. Moreover, this legislation is likewise expected to occasion a saving in time and expense to the Federal Government in its role as litigant. The cost of preparing the transcript in nearly all cases rests with the agency and is, therefore, a charge upon the Federal Treasury. Consequently, any reduction in the size of the record which must be filed could result in reducing the cost of litigation to the Government.

In addition to these considerations, the authority conferred by the bill contains sufficient flexibility to permit an appellate court to adapt its procedures to the exigencies of cases presented to it. Thus, if a litigant, either an individual or an agency, determined that the cause of justice, or considerations of time or expense, require the submission of a full record, that may be done. The purpose of the proposal is expedition, but not expedition at the expense of justice.

The bill was the subject of thorough consideration in the Judicial Conference prior to its submission to the Congress, and since its submission has been reviewed in detail by the administrative agencies. It is also appropriate to note that the agency primarily concerned with litigation involving the Federal Government, the Department of Justice, considers the proposal "a laudable effort to [p. 4] eliminate unnecessary expenditures in time and money in the review of agency orders by the courts of appeals." In short, the Department of Justice recommends enactment of the measure.

The acceptance and approval of this bill by the bench and the bar indicates that it may reasonably be calculated to accomplish the worthwhile objective which it is designed to accomplish. Consequently, the committee recommends favorable consideration of the legislation.

Attached to this report is the letter of transmittal of the Administrative Office of United States Court, dated April 5, 1957, and the report of the Department of Justice under date of June 10, 1957, to which reference was made earlier. The other agency reports on the bill are incorporated in House Report No. 842 of the 85th Congress, 1st session. In the interests of brevity they may be considered as having been incorporated by reference in this report.

VIEWS OF EXECUTIVE DEPARTMENTS

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CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

TITLE 28. UNITED STATES CODE

CHAPTER 133. REVIEW—MISCELLANEOUS PROVISIONS

* * * * * * *

2112. Record on review and enforcement of agency orders.

* * * * * * *

§ 2112. Record on review and enforcement of agency orders.

(a) The several courts of appeals shall have power to adopt, with the approval of the Judicial Conference of the United States, rules, which so far as practicable shall be uniform in all such courts prescribing the time and manner of filing and the contents of the record in all proceedings instituted in the courts of appeals to enjoin, set aside, suspend, modify, or otherwise review or enforce orders of administrative agencies, boards, commissions, and officers, to the extent that the applicable statute does not specifically prescribe such time or manner of filing or contents of the record. Such rules may authorize the agency, board, commission, or officer to file in the court a certified list of the materials comprising

the record and retain and hold for the court all such materials and transmit the same or any part thereof to the court, when and as required by it, at any time prior to the final determination of the proceeding, and such filing of such certified list of the materials comprising the record and such subsequent transmittal of any such materials when and as required shall be deemed full compliance with any provision of law requiring the filing of the record in the court. The record in such proceedings shall be certified and filed in or held for and transmitted to the court of appeals by the agency, board, commission, or officer concerned within the time and in the manner prescribed by such rules. If proceedings have been instituted in two or more courts of appeals with respect to the same order the agency, board, commission or officer concerned shall file the record in that one of such courts in which a proceeding with respect to such order was first instituted. The other courts in which such proceedings are pending shall thereupon transfer them to the court of appeals in which the record has been filed. For the convenience of the parties in the interest of justice such court may thereafter transfer all the proceedings with respect to such order to any other court of appeals. [p. 8]

(b) The record to be filed in the court of appeals in such a proceeding shall consist of the order sought to be reviewed or enforced, the findings or report upon which it is based, and the pleadings, evidence, and proceedings before the agency, board, commission, or officer concerned, or such portions thereof (1) as the said rules of the court of appeals may require to be included therein, or (2) as the agency, board, commission, or officer concerned, the petitioner for review or respondent in enforcement, as the case may be, and any intervenor in the court proceeding by written stipulation filed with the agency, board, commission, or officer concerned or in the court in any such proceeding may consistently with the rules of such court designate to be included, therein or (3) as the court upon motion of a party or, after a prehearing conference, upon its own motion may by order in any such proceeding designate to be included therein. Such a stipulation or order may provide in an appropriate case that no record need be filed in the court of appeals. If, however, the correctness of a finding of fact by the agency, board, commission, or officer is in question all of the evidence before the agency, board, commission, or officer shall be included in the record except such as the agency, board, commission, or officer concerned, the petitioner for review or respondent in enforcement, as the case may be, and any intervenor in the court proceeding by written stipulation filed with the agency, board, commission, or

officer concerned or in the court agree to omit as wholly immaterial to the questioned finding. If there is omitted from the record any portion of the proceedings before the agency, board, commission, or officer which the court subsequently determines to be proper for it to consider to enable it to review or enforce the order in question the court may direct that such additional portion of the proceedings be filed as a supplemental to the record. The agency, board, commission, or officer concerned may, at its option and without regard to the foregoing provisions of this subsection, and if so requested by the petitioner for review or respondent in enforcement shall file in the court the entire record of the proceedings before it without abbreviation.

(c) The agency, board, commission, or officer concerned may transmit to the court of appeals the original papers comprising the whole or any part of the record or any supplemental record, otherwise true copies of such papers certified by an authorized officer or deputy of the agency, board, commission, or officer concerned shall be transmitted. Any original papers thus transmitted to the court of appeals shall be returned to the agency, board, commission, or officer concerned upon the final determination of the review or enforcement proceeding. Pending such final determination any such papers may be returned by the court temporarily to the custody of the agency, board, commission, or officer concerned if needed for the transaction of the public business. Certified copies of any papers included in the record or any supplemental record may also be returned to the agency, board, commission, or officer concerned upon the final determination of review or enforcement proceedings.

(d) The provisions of this section are not applicable to proceedings to review decisions of the Tax Court of the United States or to proceedings to review or enforce those orders of administrative agencies, boards, commissions, or officers which are by law reviewable or enforceable by the district court. [p. 9]

1.8a (3) CONGRESSIONAL RECORD

1.8a (3) (a) VOL. 103 (1957), Aug. 5: Amended and passed House, pp. 13617–13618

[No Relevant Discussion on Pertinent Section]

1.8a(3) (b) VOL. 104 (1958), Aug. 14: Passed Senate, p. 17537

ENFORCEMENT OF ORDERS OF ADMINISTRATIVE AGENCIES

The bill (H. R. 6788) to authorize the abbreviation of the record on the review or enforcement of orders of administration agencies, was announced as next in order.

Mr. HRUSKA. Mr. President, may we have an explanation of the bill?

Mr. EASTLAND. Mr. President,

this bill authorizes the several courts of appeals of the United States to adopt rules authorizing the abbreviation of the transcript and other parts of the record made before Federal administrative agencies when the orders of those agencies are to be reviewed by the courts of appeals. Under several existing statutes permitting appeals to the court of appeals from the findings and orders of administrative agencies, it is necessary for the administrative agency to prepare and file the entire record of the proceedings before the administrative agency. This oftentimes results in a voluminous record, much of it not pertinent to the matters under review. Many times, likewise, the record involves other applicants not a party to the appeal.

Under the authority conferred by this bill, the courts of appeals could, by special order or by stipulation of the parties, provide for the filing of only those materials which are relevant to the issues before the court. In such matters the courts of appeals must, of necessity, have some latitude, and this legislation affords them that latitude.

The bill also provides that when petitions are filed in different circuits to review the same agency order, the jurisdiction of all the petitions shall rest with the court of appeals in which the first petition is filed but that court will have authority to transfer such cases to another court of appeals if it appears that the convenience of the parties and the interests of justice would be served. Under existing law the agency, by selecting the court in which it files the record, determines which court shall have jurisdiction.

Information submitted to the committee indicated that the adoption of this legislation would result in the saving of time on the part of the court of appeals. Since it is now incumbent upon the Federal agencies to prepare the record for filing in the courts of appeals, it is also likely that this legislation would result in a saving of time and expense on the part of the Federal administrative agencies.

For these reasons, the committee has recommended that the legislation be favorably considered.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the bill was considered, ordered to a third reading, read the third time, and passed.

[p. 17537]

1.9 COURTS OF APPEALS; CERTIORARI; APPEALS; CERTIFIED QUESTIONS. AS AMENDED

28 U.S.C. §1254 (1948)

[Referred to in 7 U.S.C. §135b (d), 21 U.S.C. §§346a (i) (5), 348(g) (5), 15 U.S.C. §1474(b) (5)]

COURTS OF APPEALS; CERTIORARI; APPEAL; CERTIFIED QUESTIONS

28 § 1254

Cases in the courts of appeals may be reviewed by the Supreme Court by the following methods:

(1) By writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree;

(2) By appeal by a party relying on a State statute held by a court of appeals to be invalid as repugnant to the Constitution, treaties or laws of the United States, but such appeal shall preclude review by writ of certiorari at the instance of such appellant, and the review on appeal shall be restricted to the Federal questions presented;

(3) By certification at any time by a court of appeals of any question of law in any civil or criminal case as to which instructions are desired, and upon such certification the Supreme Court may give binding instructions or require the entire record to be sent up for decision of the entire matter in controversy. June 25, 1948, c. 646, 62 Stat. 928.

1.9a APPEALS TO AND/OR FROM THE CIRCUIT COURT OF APPEALS

March 3, 1911, P.L. 61-475, §§239, 240, 36 Stat. 1157

SEC. 239. In any case within its appellate jurisdiction, as defined in section one hundred and twenty-eight, the circuit court of appeals at any time may certify to the Supreme Court of the United States any questions or propositions of law concerning which it desires the instruction of that court for its proper decision; and thereupon the Supreme Court may either give its instruction on the questions and propositions certified to it, which shall be binding upon the circuit court of appeals in such case, or it may require that the whole record and cause be sent up to it for its consideration, and thereupon shall decide the whole matter in controversy in the same manner as if it had been brought there for review by writ of error or appeal.

SEC. 240. In any case, civil or criminal, in which the judgment or decree of the circuit court of appeals is made final by the provisions of this Title, it shall be competent for the Supreme Court to require, by certiorari or otherwise, upon the petition of any party thereto, any such case to be certified to the Supreme Court for its review and determination, with the same power and authority in the case as if it had been carried by appeal or writ of error to the Supreme Court.

[p. 1157]

1.9a (1) SENATE SPECIAL JOINT COMMITTEE ON REVISION AND CODIFICATION OF LAWS

S. REP. No. 388 (parts 1 & 2), 61st Cong., 2d Sess. (1910)

S. 7031

REVISION OF LAWS—JUDICIARY TITLE

MARCH 14, 1910.—Ordered to be printed

Mr. HEYBURN, from the Special Joint Committee on Revision and Codification of the Laws of the United States, submitted the following

REPORT—PART 1

[To accompany S. 7031]

The Joint Committee on Revision and Codification of the Laws of the United States submit herewith an explanatory statement of each section contained in Senate Bill 7031.

This bill includes the first 12 chapters of the judiciary title, being title 13 of the Revised Statutes of 1878, with all legislation amending, repealing, or modifying the same. Chapter 13, on habeas corpus, chapter 15, on juries, and chapters 20 and 21, on the Court of Claims, are included within this bill. [p. 1]

Section 239:

This section states concisely the appellate jurisdiction of the Supreme Court conferred upon it by the bankruptcy act of July 1, 1898 (2 Supp., 853). The only changes in phraseology are those necessary to separate the provisions relating to the Supreme Court from those relating to other courts.

Section 240:

Existing law; no change whatever. [p. 85]

1.9a (2) HOUSE COMMITTEE ON REVISION OF THE LAWS

H.R. Doc. No. 783, (part 1), 61st Cong., 2d Sess. (1910)

REVISION AND CODIFICATION OF THE LAWS, ETC.

MARCH 15, 1910.—Referred to the Committee on Revision of the Laws and ordered to be printed

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Mr. MOON, of Pennsylvania, from the Special Joint Committee on the Revision of the Laws, submitted the following report:

The House members of the Special Joint Committee on the Revision of the Laws, appointed under public resolution No. 58 of the Sixtieth Congress, second session, to examine, consider, and submit to Congress recommendations upon the revision and codification of the laws prepared by the statutory Revision Commission, heretofore authorized to revise and codify the laws of the United States, having had under consideration the judiciary title reported by that commission, and deeming it both necessary and expedient to make certain changes, additions, and omissions, report in lieu thereof the accompanying bill and submit the following report thereon:

* * * * * * *

[p. 1]

Section 239:

This section states concisely the appellate jurisdiction of the Supreme Court conferred upon it by the bankruptcy act of July 1, 1898 (2 Supp., 853). The only changes in phraseology are those necessary to separate the provisions relating to the Supreme Court from those relating to other courts.

Section 240:

Existing law; no change whatever.

[p. 89]

1.9a (3) HOUSE COMMITTEE ON REVISION OF THE LAWS

H.R. REP. No. 818, 61st Cong., 2d Sess. (1910)

REVISION OF LAWS

MARCH 23, 1910.—Referred to the House Calendar and ordered to be printed

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Mr. MOON, of Pennsylvania, from the Committee on Revision of the Laws, submitted the following

REPORT

[To accompany H.R. 23377]

The Committee on the Revision of the Laws, to whom was referred the bill H.R. 23377, submit the following report:

This bill having previously been considered by the Joint Committee on the Revision of the Laws, to which it was committed under public resolution No. 58, Sixtieth Congress, second session, which committee made a complete report thereon (H. Doc. No. 783, parts 1 and 2), this committee, upon the basis of that report, reports the same back to the House with favorable recommendation.

[p. 1]

1.9a (4) COMMITTEE OF CONFERENCE

S. DOC. No. 848, 61st Cong., 3rd Sess. (1911)

REVISION AND CODIFICATION OF THE LAWS.

MR. HEYBURN presented the following

CONFERENCE REPORT RELATIVE TO THE REVISION AND CODIFICATION OF THE LAWS

MARCH 1, 1911.—Ordered to be printed

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill S. 7031, being a bill to codify, revise, and amend the laws relating to the judiciary, having met, after full and free conference, have agreed to recommend, and do recommend, to their respective Houses as follows:

That the Senate agree to the House amendment, with amendments to sections 2, 13, 14, 21, 24, 28, 29, 30, 40, 56, 70, 76, 78, 88, 91, 92, 99, 103, 106, 112, 118, 126, 128, 140, 151, 152, 178, 182, 186, 201, 207, 226 227, 228, 229, 240, 250, 251, 259, 284, 289, 298, 301.

That the House agree to the amendments proposed by the Senate conferees, as follows:

(The references to section numbers and pages are to the bill as reported by the conferees and not to the bill as it passed the House or Senate.)

[p. 1]

Section 240. On page 192, in line 19, after the word "case" insert *civil or criminal;* in line 22, after the word "otherwise," insert *upon the petition of any party thereto.*

[p. 6]

1.9a (5) CONGRESSIONAL RECORD, VOL. 46 (1911)

1.9a (5) (a) Feb. 8: Amended and passed Senate, p. 2140

[No Relevant Discussion on Pertinent Section]

1.9a (5) (b) Feb. 23: Amended and passed House, p. 3220

[No Relevant Discussion on Pertinent Section*]

1.9a (5) (c) March 2: Senate agreed to conference report, p. 3853

[No Relevant Discussion on Pertinent Section*]

1.9a (5) (d) March 2: House agreed to conference report, pp. 3998, 4000, 4012

[No Relevant Discussion on Pertinent Section*]

1.9b JUDICIAL CODE AMENDMENTS OF 1925

February 13, 1925, P.L. 68–415, §1, 43 Stat. 938

SEC. 1.

* * * * * * *

"SEC. 239. In any case, civil or criminal, in a circuit court of appeals, or in the Court of Appeals of the District of Columbia, the court at any time may certify to the Supreme Court of the United States any questions or propositions of law concerning which instructions are desired for the proper decision of the cause; and thereupon the Supreme Court may either give binding instructions on the questions and propositions certified or may require that the entire record in the cause be sent up for its consideration, and thereupon shall decide the whole matter in controversy in the same manner as if it had been brought there by a writ of error or appeal."

SEC. 240. (a) In any case, civil or criminal, in a circuit court of appeals, or in the Court of Appeals of the District of Columbia, it shall be competent for the Supreme Court of the United States, upon the petition of any party thereto, whether Government or other litigant, to require by certiorari, either before or after a [p. 938] judgment or decree by such lower court, that the cause be certified to the Supreme Court for determination by it with the same power and authority, and with like effect, as if the cause had been brought there by unrestricted writ of error or appeal.

"(b) Any case in a circuit court of appeals where is drawn in question the validity of a statute of any State, on the ground of its being repugnant to the Constitution, treaties, or laws of the United States, and the decision is against its validity, may, at the election of the party relying on such State statute, be taken to the Supreme

Court for review on writ of error or appeal; but in that event a review on certiorari shall not be allowed at the instance of such party, and the review on such writ of error or appeal shall be restricted to an examination and decision of the Federal questions presented in the case.

"(c) No judgment or decree of a circuit court of appeals or of the Court of Appeals of the District of Columbia shall be subject to review by the Supreme Court otherwise than as provided in this section."

[p. 939]

1.9b (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 1075, 68th Cong., 2d Sess. (1925)

JURISDICTION OF CIRCUIT COURTS OF APPEALS AND OF THE SUPREME COURT

JANUARY 6, 1925.—Referred to the House Calendar and ordered to be printed

Mr. GRAHAM, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 8206]

The Committee on the Judiciary, to whom was referred the bill H.R. 8206, after hearings and consideration, report favorably thereon with amendments, and recommend that the bill as amended do pass.

The committee amendments are as follows:

On page 2, line 11, strike out "Constituton" and insert "Constitution."

On page 5, in line 5, strike out "taken" and insert "applied for."

On page 8, after line 5, insert the following paragraph:

> (5) Section 316 of "An act to regulate interstate and foreign commerce in livestock, livestock products, dairy products, poultry, poultry products, and eggs, and for other purposes," approved August 15, 1921.

On page 10, in line 11, strike out "writ of error or."

On page 11, in line 9, add the following sentence:

> A circuit judge shall have the same power to grant writs of habeas corpus within his circuit that a district judge has within his district; and the order of the circuit judge shall be entered in the records of the district court of the district wherein the restraint complained of is had.

On page 13, in line 5, insert between "Supreme Court" and "before the court" the words "from a circuit court of appeals or the

Court of Appeals of the District of Columbia."

On page 13, between lines 8 and 9, insert two paragraphs as follows:

(c) No writ of error or appeal intended to bring any judgment or decree before a circuit court of appeals for review shall be allowed unless application therefor be duly made within three months after the entry of such judgment or decree.

(d) In any case in which the final judgment or decree of any court is subject to review by the Supreme Court on writ of certiorari, the execution and enforcement of such judgment or decree may be stayed for a reasonable time to enable the party aggrieved to apply for and to obtain a writ of certiorari from the Supreme Court. The stay may be granted by a judge of the court rendering the judgment or decree or by a justice of the Supreme Court, and may be conditioned on the giving of good and sufficient security, to be [p. 1] approved by such judge or justice, that if the aggrieved party fails to make application for such writ within the period allotted therefor, or fails to obtain an order granting his application, or fails to make his plea good in the Supreme Court, he shall answer for all damages and costs which the other party may sustain by reason of the stay.

On page 17, above line 1, insert the following:

An act entitled "An act to amend the Judicial Code, in reference to appeals February 17, 1922.

An act entitled "An act to amend the Judicial Code, in reference to appeals and writs of error," approved September 14, 1922.

On page 15, line 20, strike out "1916" and insert in lieu thereof "1917."

THE BILL

It is one prepared by justices of the Supreme Court, not as volunteers, but in answer to a proper request to do so. A committee of justices carefully considered the subject for a long time and then framed a tentative measure, which was submitted to all the justices and approved by them.

THE OBJECT

The bill is designed to lessen the number of cases which under existing law reach the Supreme Court. It will not lighten the burden or relieve the Supreme Court of work, but will remove from their consideration a class of cases which now burden the docket and have no public interest or value, and give the Supreme Court time to hear and determine those cases which should alone engage their attention. That court is more than a year behind on its list of pending cases, and this condition will surely be aggravated each year if the court is left without relief. It is hoped by this bill to enable the court to overtake its work, and keep up with it. Having to hear numbers of cases of a trivial character, or cases brought really for delay, or to wear out an adversary, the court is hindered from hearing and determining more important cases and from efficiently functioning in the performance of its highest duty of interpreting the Constitution and preserving uniformity of decision by the intermediate courts of appeals.

The Supreme Court will always have plenty to do whether this bill passes or not. The problem is whether the time and attention and energy of the court shall be devoted to matters of large public concern, or whether they shall be consumed by matters of less concern, without especial general interest, and only because the litigant wants to have the court of last resort pass upon his right.

Although final decisions will be multiplied in the intermediate courts of appeals by this bill, if it shall become a law, yet every case now reviewable by the Supreme Court under existing law will still be reviewable by that tribunal whenever a question is presented which is of sufficient importance in the opinion of the Supreme Court. The obligatory appeal and writ of error is limited, and a very broad and comprehensive discretionary power is given by certiorari. Through this discretionary power there can and will be a weeding out of all trivial and unimportant cases: cases brought for delay; cases which cover matters already decided, etc., so that rapidity of action will be achieved; and the public questions—the vital and important ones—will be reviewed, considered, and decided. [p. 2]

The change of many cases from the obligatory class to the certiorari class will enable the court by a denial of the writ to give immediate notice to the parties of the disposition of their cases. It will greatly reduce the number of those who have to wait until their cases are reached on the docket and relieve them of the needless suspense and delay to which they are now subjected. The opportunity of taking cases to the Supreme Court merely for delay will be almost entirely removed.

Lest it should be thought that the increase of discretionary jurisdiction might impair the administration of justice and lead to partial hearings and not secure a decision by the whole court, it is proper to call attention to the very thorough and complete system by which discretionary jurisdiction is exercised. In granting or refusing a prayer for a certiorari the petitioner gets the judgment of the whole court. The application is not disposed of by a single justice. The luminous and informing statement of Mr. Justice Van Devanter tells the whole story:

> "While the authority of the Supreme Court to take cases on petition for certiorari is spoken of as a discretionary jurisdiction, this does not mean that the

court is authorized merely to exercise a will in the matter but rather that the petition is to be granted or denied according to a sound judicial discretion. What actually is done may well be stated here with some particularity. The party aggrieved by the decision of the circuit court of appeals and seeking a further review in the Supreme Court is required to present to it a petition and accompanying brief, setting forth the nature of the case, what questions are involved, how they were decided in the circuit court of appeals, and why the case should not rest on the decision of that court. The petition and brief are required to be served on the other party, and time is given for the presentation of an opposing brief. When this has been done copies of the printed record as it came from the circuit court of appeals and of the petition and briefs are distributed among the members of the Supreme Court, and each judge examines them and prepares a memorandum or note indicating his view of what should be done.

In conference these cases are called, each in its turn, and each judge states his views in extenso or briefly as he thinks proper; and when all have spoken any difference in opinion is discussed and then a vote is taken. I explain this at some length because it seems to be thought outside that the cases are referred to particular judges, as, for instance, that those coming from a particular circuit are referred to the justice assigned to that circuit, and that he reports on them, and the others accept his report. That impression is wholly at variance with what actually occurs.

We do not grant or deny these petitions merely according to a majority vote. We always grant the petition when as many as four think that it should be granted and sometimes when as many as three think that way. We proceed upon the theory that, if that number out of the nine are impressed with the thought that the case is one that ought to be heard and decided by us, the petition should be granted."

PROPOSED CHANGES IN SUPREME COURT'S METHOD OF REVIEW

The great object of this bill is to reduce the number of cases in which there is an appeal or writ of error as of right, and increase those in which only a certiorari or a certificate can bring the case before the Supreme Court.

The courts over which the Supreme Court in this bill exercise a direct review are:

First. The State supreme courts.

Second. The district courts of the United States.

Third. The circuit courts of appeal.

Fourth. Court of Appeals of the District of Columbia.

Fifth. Court of Claims.

[p. 3]

Sixth. Supreme Court of the Philippines.

The only cases in the proposed bill in which the Supreme Court exercises obligatory jurisdiction—that is, by writ of error or appeal—are:

First. Over the final judgments or decrees of State courts of last resort.

(a) In cases in which the validity of the statute of a State under the Federal Constitution has been drawn in question and its validity sustained.

(b) Where the validity of a Federal statute or treaty has been drawn in question and its validity denied.

Second. In four special classes of cases from the district court, which are:

(a) Appeals from decrees in equity in suits brought by the United States to enforce the antitrust or interstate commerce acts.

(b) Writs of error in criminal cases brought by the United States to judgments of the district courts in which the United States has been defeated by a ruling of the district court, and where the defendant has not been exposed to jeopardy or acquitted by a verdict of the jury.

(c) Appeals from interlocutory injunctions against enforcement of State statutes by any officer of the State, or against the exercise of an authority of a board acting under a State statute.

(d) Appeals from interlocutory and final decrees of injunction and suspension of orders of Interstate Commerce Commission in district courts.

In all other cases, to wit, *(a)* final judgments in the State supreme courts which involve Federal constitutional questions other than those above mentioned; *(b)* all cases in the circuit courts of appeals; *(c)* all cases in the Court of Appeals of the District of Columbia; *(d)* all cases in the Court of Claims; and *(e)* certain classes of cases from the Supreme Court of the Philippines, the only method of review is either by certiorari from the Supreme Court, or (except from the Philippines) by certificate by the inferior court of questions. Writs of certiorari to State supreme courts, to the Court of Claims, and to the Supreme Court of the Philippines, can only issue after final judgments in those courts. Such writs may issue to circuit courts of appeals and to the Court of Appeals of the District of Columbia, before or after judgment, but if before judgment, the application must be made before the hearing and submission in those courts.

It is impossible to estimate how many cases these changes will transfer from the obligatory jurisdiction of the Supreme Court, as it is under existing law, to the discretionary jurisdiction of the Supreme Court, but it will be such a substantial number as greatly to help the court to catch up with its docket and to keep up with it thereafter.

JURISDICTION OF THE CIRCUIT COURTS OF APPEALS

We come now to the present and the proposed jurisdiction of the circuit courts of appeal, from which we can get some idea of the change in the appellate jurisdiction of the Supreme Court of cases from the circuit court of appeals. Under the present law, the circuit court of appeals has appellate jurisdiction in respect to all cases [p. 4] from the district court, except the four instances of direct appeal to the Supreme Court already mentioned, as still retained in the proposed bill, and also except in cases in which appeal can now be taken from the district court directly to the Supreme Court, on the sole question of jurisdiction of the district court as a Federal court, on a question involving the construction and application of the Constitution of the United States, or the construction of a treaty and in prize cases, and in suits therein against the United States for claims not exceeding $10,000 under what is known as the Tucker Act, a jurisdiction of the district courts concurrent with that of the Court of Claims. The new bill abolishes this direct review of the Supreme Court in all these except the four instances first mentioned and makes them subject to review by writ of error or appeal in the circuit court of appeals, and thence they are only reviewable by certiorari or certificate in the Supreme Court.

EXISTING LAW AS TO REVIEW OF CASES IN CIRCUIT COURTS OF APPEALS

Circuit courts of appeal now have final appellate jurisdiction in all cases from the district courts wherein the amount involved does not exceed $1,000, in diverse citizenship cases, in patent cases, in copyright cases, in revenue cases, in criminal cases, in admiralty cases, in trade-mark cases, and in bankruptcy proceedings, controversies, and cases, in cases under the employers' liability act, in cases under the hour of service act and cases under the safety appliance act, and also in habeas corpus cases. These can under existing law only reach the Supreme Court by certiorari or certificate. In all other cases coming up to the circuit court of appeals from the district courts, there is, by existing law, an appeal or writ of error as of right to the Supreme Court.

WRITS OF ERROR AND APPEALS FROM CIRCUIT COURTS OF APPEALS TO THE SUPREME COURT CUT OFF BY THE BILL

Just what cases may, by existing law, be taken to the Supreme Court from the circuit court of appeals by writ of error or appeal it is difficult to state in a brief way. Section 24 of the Judicial Code contains a list of 25 classes of civil suits that are cognizable by district courts of the United States and are reviewable by the circuit court of appeals. They embrace suits so rarely brought as to be regarded as nearly obsolete, e. g., "suits arising under any law relating to the slave trade." On the other hand, they do include such classes as civil suits.

(1) Brought by the United States, or by any officer thereof authorized by law to sue.

(2) Between citizens of the same State claiming lands under grants from different States.

(3) Where more than $3,000 is involved and the suit arises under the Constitution or laws or treaties of the United States.

(4) Seizures on land or waters not within admiralty or maritime jurisdiction.

(5) Cases arising under the postal laws.

(6) Suits and proceedings under any law regulating commerce, except such as may be covered by special statutes already mentioned.

(7) Civil suits and proceedings for enforcement of penalties and forfeitures incurred under any law of the United States.

[p. 5]

(8) Suits for damages by officers and persons for injury done him in protection or collection of United States revenue or to enforce right of citizens to vote.

(9) Suits for damages by citizens injured in their Federal constitutional rights.

(10) Suits against consuls and vice consuls.

(11) Suits under immigration and contract labor laws.

(12) Private suits under the antitrust act.

(13) Suits by Indians or part blood Indians for allotment under any law or treaty.

(14) Suits by tenants in common or joint tenant for partition of land in which the United States is also tenant in common or joint tenant.

All these cases can now be heard in review by the circuit court of appeals and then in the Supreme Court as of right, unless, as may happen, they are also patent, revenue, criminal, or admiralty cases, or in some other class now made final in the circuit court of appeals. Under the proposed bill, the decisions in them in the circuit court of appeals are to be final and they can only reach the Supreme Court by certiorari or certificate.

REVIEW OF COURTS OF ALASKA AND DEPENDENCIES

Under existing law, appellate jurisdiction over the courts of our dependencies (except those of the Philippines), and over the district court of the Territory of Alaska, and over the United States court for China, is distributed between first, third, fifth, and ninth circuit court of appeals. Cases from the Supreme Courts of Hawaii and Porto Rico, as distinguished from United States district courts, so called therein, are now reviewable in the Supreme Court of the United States, when they present questions similar to those which are reviewable in that court from State courts of last resort; and some cases from the district court of Alaska also go to the Supreme Court direct. All these cases from the dependencies, from Alaska, and from the United States Court for China, under the new bill, which are reviewable at all, no matter what they involve, are to be carried by appeal or writ of error to the designated circuit court of appeals. This final jurisdiction of circuit courts of appeals under the new bill includes Porto Rico, Hawaii, both supreme and district courts, the District Court of the Virgin Islands, the Court of the Canal Zone, the United States Court for China, and the United States District Court for Alaska. The review of these is final in the designated circuit court of appeals, except that there is the same opportunity for review by certiorari and certificate in the Supreme Court as in other cases in such circuit courts of appeals. A few changes have been made in the limit of the pecuniary amount involved in cases which may be appealed from these dependency and territorial courts, for the purpose of uniformity, but this is not important.

EFFECT OF BILL ON REVIEW OF CASES IN THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA

All cases from the Supreme Court of the District of Columbia are, by the proposed law, appealable to the Court of Appeals of the District, including all forms of cases, controversies, and proceed- [p. 6] ings in bankruptcy and cases in habeas corpus, and the judgments of the Court of Appeals of the District are final therein, to be reviewed by the Supreme Court only by certiorari and certificate.

EFFECT OF BILL ON REVIEW OF CASES FROM COURT OF CLAIMS

The decisions of the Court of Claims are final, only to be reviewed in the Supreme Court by certiorari or certificate.

REMEDIAL PROVISIONS

In addition to these changes in jurisdiction, there are in the proposed bill some remedial amendments of a general character.

First. The time for application for writ of error or appeal or certiorari to the Supreme Court has been enlarged from the present limit of three months, and six months for the Philippines, by a provision for a further allowance of 60 days upon order of a justice of the Supreme Court upon a proper showing.

Second. There is a reenactment of the present remedial provision as to parol proof of amount in controversy, where it is necessary for the jurisdiction and is not adequately shown either in the trial court or in the appellate court.

Third. There is the remedial provision that if a man takes out a writ or error when he should have taken out an appeal, or vice versa, it shall be considered by the court to be a right writ. This is at present the law; but in addition to this it is provided that where one takes out a writ of error from the Supreme Court of the United States to a State supreme court, and it turns out that it should have been a certiorari, the writ of error may be considered by the court as an application for certiorari and acted upon as such.

Fourth. There is a very necessary remedial provision for the substitution in suits in the Supreme Court for public officers who have ceased to be such, of their successors, as parties in suits brought by them or against them. This is now the case with respect to officers of the United States; but it is not the case with respect to officers of the States, of the counties, or of the municipalities who are plaintiffs or defendants in the Supreme Court. This is a great injustice, because one may begin a suit in a district court of the United States against officers of a State, county, or city, or such officers may bring a suit therein, and not reach the Supreme Court for review before their successors have been elected. Now, no substitution can be made, the case abates, and the action goes for nothing. Under this provision, the new State, county, and city officers may be substituted after notice to them and if such substitution is shown not to work them injustice.

Fifth. There is another provision that takes away all rights of corporations organized by Congress to seek the Federal court on that ground. This enlarges a present provision of a similar tenor which applies only to railway corporations.

THE WAY OF APPEAL WILL CEASE TO BE A "TRAP"

Besides the relief of the Supreme Court docket, and turning aside a large number of cases from that court and making the decisions of the circuit courts of appeals final in many cases and only reviewable by certiorari—this bill should become a law be- [p. 7] cause it clarifies and makes understandable the law governing appeal whether by writ of error, appeal, or certiorari.

It was well said by the Chief Justice at the hearing that the present laws are a "trap" in procedure.

This bill will simplify the law of appellate jurisdiction, relieve lawyers and litigants of uncertainties and perils which can not always be avoided even by the well-equipped and trained practitioner.

The statutes fixing the jurisdiction of the Supreme Court and the circuit courts of appeals are to-day fragmentary. They are scattered. Some are in the Revised Statutes of 1878; some in the Judicial Code of 1911; and others consist of amendments appearing here and there in many volumes of the Statutes at Large. They are difficult to find and when found are neither harmonious nor plain. Mr. Justice Van Devanter very forcefully pictured this state of the law when he said in the hearing:

> The circuit court of appeals act passed in 1891, besides defining the jurisdiction of those courts, contained many provisions relating to the jurisdiction of the Supreme Court. Most of these provisions and many amendatory enactments were brought together advantageously in the Judicial Code of 1911. But that was not a complete revision. It left some statutes, old ones, untouched and did not bring them forward; so no one could examine the Judicial Code and act safely merely upon what appeared there. It would be necessary to go back and search the Revised Statutes and the intermediate Statutes at Large to determine what course to pursue in invoking a review by either a circuit court of appeals or the Supreme Court. Not only so, but the statutes when found left it uncertain in some classes of cases in the district courts whether the case could be carried directly to the Supreme Court or must go to the circuit court of appeals.
>
> Since the Judicial Code of 1911 many statutes have been enacted which bear upon the jurisdiction of these courts—a statute would be adopted at one time with respect to one class of cases, and another statute would be adopted at another time with respect to another class. These statutes have been multiplied until now they are not harmonious. Neither do they follow a consistent plan or theory.
>
> The situation now is that in the Supreme Court a good many cases have to be dismissed, their merits left untouched, because they have been brought there from a district court when they should have gone to a circuit court of appeals, or because they have been brought from a circuit court of appeals on writ of error or appeal when they could come up only on certiorari, or because they have been brought from a State court on writ of error where certiorari was the only admissible mode of bringing them up.
>
> These mistakes are generally attributable to the fact that the practitioner has found a part of the statues and not the rest. Sometimes the mistake is mere carelessness; but it not infrequently happens that lawyers who stand high in their profession at home mistake their remedy or the mode of invoking it either because they do not find the controlling statute or because they have difficulty in reconciling it with others.

Your committee expresses its deep obligation to the Chief Justice and justices of the Supreme Court for their help not only in preparing this bill but explaining it thoroughly.

The proposed legislation was recommended by the President in his message of December 3, 1924, to the Congress. [p. 8]

1.9b (2) CONGRESSIONAL RECORD, VOL. 66 (1925)

1.9b (2) (a) Feb. 2: Amended and passed House, pp. 2877–2880

[No Relevant Discussion on Pertinent Section]

1.9b (2) (b) Feb. 3: Amended and passed Senate, p. 2928

[No Relevant Discussion on Pertinent Section]

1.9b (2) (c) Feb. 4: House agreed to Senate amendments, p. 3005

JURISDICTION OF THE CIRCUIT COURTS OF APPEALS AND OF THE SUPREME COURT

Mr. GRAHAM. Mr. Speaker, I call up the bill (H. R. 8206) to amend the Judicial Code and to further define the jurisdiction of the circuit courts of appeals and of the Supreme Court, and for other purposes, with a Senate amendment thereto, and move to concur in the Senate amendment.

The Clerk read the Senate amendment.

Mr. GRAHAM. Mr. Speaker, I yield two minutes to the gentleman from Texas. [Mr. BLANTON].

Mr. BLANTON. Mr. Speaker, the last bill that was agreed to a moment ago had all after the enacting clause stricken out by the Senate, and then a reenacting of our 19 pages of language with one little change. We still have a 19 page bill, but it has become a Senate instead of a House bill. The Senate has stricken out every word of our bill after the enacting clause and has then put back all of the language of our bill, embracing nearly 20 pages, except two little changes. Why was that necessary? Some of the best lawyers in the Nation are on this Judiciary Committee of the House. Are they not able to write a bill that can be passed into law without its being stricken out? Why is it that every bill we pass in the House and send to another body, regardless of its size and the number of its pages, has to have all of it stricken out after the enacting clause and practically the same language put back into it page after page, with just a few changes? Why do they not insert their amendments in our House bills? I am protesting against their practice. It ought not to be continued. If a bill which we send to the other body is meritorious but needs a little change, the change ought to be made by their amendment; they ought not to rewrite word for word our entire bill, and they ought not to require us to read 19 pages of matter which they insert and which they send back to us to find out the changes they have made. It puts double work on the committee and it puts double work on the membership of the House and I hope that they will stop it. [Applause.]

Mr. JONES. Mr. Speaker, will the gentleman yield?

Mr. GRAHAM. Yes.

Mr. JONES. What changes did the Senate make in the bill?

Mr. GRAHAM. They made one change to meet the objection of the gentleman from Illinois [Mr. DENISON], made at the time we passed the bill. I had given a promise that I would help him introduce any change that might be necessary to properly safeguard what he was seeking. He went to the committee of judges and the matter was agreed on, and two amendments were inserted, and then there was one formal amendment inserted by the Senator from Massachusetts, Mr. WALSH. Otherwise the bill is exactly the same as it passed the House.

Mr. JONES. What was the other amendment?

Mr. GRAHAM. The Judiciary Committee considered it and have authorized concurrence in the amendments of the Senate, unanimously.

Mr. JONES. I understand the amendment that the gentleman from Illinois referred to, in respect to the jurisdiction of the Panama Canal, but what does the other amendment refer to?

Mr. GRAHAM. I can not point it out as I have not the bill before me, but it is a simple change. It does not involve any organic change or even an important change. It was inserted to satisfy the objection of Senator WALSH.

The SPEAKER. The question is on agreeing to the Senate amendment.

The Senate amendment was agreed to. [p. 3005]

1.9c WRITS OF ERROR ABOLISHED AMENDMENTS

January 31, 1928, P.L. 70–10, §1, 45 Stat. 54

CHAP. 14.—An Act In reference to writs of error.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the writ of error in cases, civil and criminal, is abolished. All relief which heretofore could be obtained by writ of error shall hereafter be obtainable by appeal.

SEC. 2. That in all cases where an appeal may be taken as of right it shall be taken by serving upon the adverse party or his attorney of record, and by filing in the office of the clerk with whom the order appealed from is entered, a written notice to the effect that the appellant appeals from the judgment or order or from a specified part thereof. No petition of appeal or allowance of an appeal shall be required: *Provided, however,* That the review of judgments of State courts of last resort shall be petitioned for and allowed in the same form as now provided by law for writs of error to such courts.

Approved, January 31, 1928. [p. 54]

1.9c (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 370, 70th Cong., 1st Sess. (1928)

IN REFERENCE TO WRITS OF ERROR

JANUARY 24, 1928.—Referred to the House Calendar and ordered to be printed

Mr. DYER, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 1801]

The Committee on the Judiciary to whom was referred the bill S. 1801, after hearing (67th Cong., serial 25, p. 18) and consideration, reports the same favorably and recommends that the bill do pass.

This bill is merely to simplify procedure by abolishing writs of error and providing that the relief which heretofore could be obtained by writ of error shall hereafter be obtainable by appeal. It has been repeatedly indorsed by the American Bar Association. [p. 1]

1.9c (2) CONGRESSIONAL RECORD, VOL. 69 (1928)

1.9c (2) (a) Jan. 14: Discharged and passed Senate without amendment, p. 1486

WRITS OF ERROR

The bill (S. 1801) in reference to writs of error was considered as in Committee of the Whole, and was read, as follows:

Be it enacted, etc., That the writ of error in cases, civil and criminal, is abolished. All relief which heretofore could be obtained by writ of error shall hereafter be obtainable by appeal.

SEC. 2. That in all cases where an appeal may be taken as of right it shall be taken by serving upon the adverse party or his attorney of record, and by filing in the office of the clerk with whom the order appealed from is entered, a written notice to the effect that the appellant appeals from the judgment or order or from a specified part thereof. No petition of appeal or allowance of an appeal shall be required: *Provided, however*, That the review of judgments of State courts of last resort shall be petitioned for and allowed in the same form as now provided by law for writs of error to such courts.

Mr. WALSH of Montana. I may say that this is a bill recommended by the American Bar Association for the purpose of simplifying the practice of getting appeals into the Supreme Court of the United States.

The bill was reported to the Senate without amendment, ordered to be engrossed for a third reading, read the third time, and passed.

[p. 1486]

1.9c (2) (b) Jan. 25: Passed House, without amendment, p. 2040

[No Relevant Discussion on Pertinent Section]

1.9d DISTRICT OF COLUMBIA COURT OF APPEALS ACT

June 7, 1934, P.L. 73–298, 48 Stat. 926

[CHAPTER 426.]

AN ACT

To amend an Act of Congress approved February 9, 1893, entitled "An Act to establish a court of appeals for the District of Columbia, and for other purposes."

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the court established by the Act of February 9, 1893 (27 Stat. 434), entitled "An Act to establish a court of appeals for the District of Columbia, and for other purposes", shall hereafter be known as the United States Court of Appeals for the District of Columbia.

Approved, June 7, 1934.

[p. 926]

1.9d (1) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 917, 73rd Cong., 2d Sess. (1934)

TO CHANGE THE NAME OF THE COURT OF APPEALS TO THE DISTRICT OF COLUMBIA TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA

APRIL 26 (calendar day, MAY 7), 1934.—Ordered to be printed

Mr. KING, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 3524]

The Committee on the Judiciary, having had under consideration the bill (S. 3524) to amend an act of Congress approved February 9, 1893, entitled "An act to establish a court of appeals for the District of Columbia, and for other purposes", report the same favorably to the Senate and recommend that the bill do pass.

The sole purpose of this bill is to correct a misnomer in the title of the court. The present title—"Court of Appeals of the District of Columbia"—implies that the court is merely an appellate court for matters arising in the District of Columbia. It has such local appellate jurisdiction, but in addition its national jurisdiction is broader than that of any other national court except the Supreme Court of the United States. Among the national questions being constantly considered by this court are those involving the Transportation Act and the Interstate Commerce Act; mandamus proceedings in relation to Indian treaties; equity proceedings in relation to public lands; proceedings for the enforcement of the postal laws; suits against the Federal Power Commission; suits against the Civil Service Commission; suits against the Alien Property Custodian; suits against the Federal Trade Commission; title to patented public lands; appeals from the Board of Tax Appeals without relation to the residence of the taxpayer; proceedings under War Veterans' Act; proceedings in relation to irrigation projects; proceedings in relation to cancelation of mineral and oil leases; proceedings in relation to the admission of aliens; the enrollment of Indians; suits under the antitrust laws; and appeals from the Radio Commission.

[p. 1]

1.9d (2) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 1748, 73rd Cong., 2d Sess. (1934)

TO CHANGE THE NAME OF THE COURT OF APPEALS OF THE DISTRICT OF COLUMBIA

MAY 23, 1934.—Referred to the House Calendar and ordered to be printed

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Mr. SUMNERS, of Texas, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 9437]

The Committee on the Judiciary, to whom was referred the bill (H.R. 9437) to amend an act approved February 9, 1893, "An act to establish a Court of Appeals for the District of Columbia, and for other purposes," after consideration, report the same favorably to the House with recommendation that the bill do pass.

This bill changes the name of the Court of Appeals of the District of Columbia to "The United States Court of Appeals for the District of Columbia". It is felt that this change in name will help to correct an erroneous impression which is frequently found to exist among the laity, and the bar as well, that this court is simply a local court of the District of Columbia, whereas, in fact, it is a United States court with extensive national jurisdiction in addition to its jurisdiction as an appellate court of the District of Columbia.

As pointed out by Mr. Justice Groner, one of the five members of the court, the court deals with many questions which have no relation to the District of Columbia. These involve the Transportation Act and the Interstate Commerce Act; mandamus proceedings in relation to Indian treaties; equity proceedings in relation to public lands; proceedings for the enforcement of the postal laws; suits against the Federal Power Commission; suits against the Civil Service Commission; suits against the Alien Property Custodian; suits against the Federal Trade Commission; title to patented public lands; appeals from the Board of Tax Appeals without relation to the residence of the taxpayer; proceedings under War Veterans' Act; proceedings in relation to irrigation projects; proceedings in relation to cancelation of mineral and oil leases; proceedings in relation to the admission of aliens; the enrollment of Indians; suits under the antitrust laws; and appeals from the Radio Commission.

[p. 1]

Mr. Justice Groner's communication addressed to the Chairman of the Senate Committee on the Judiciary, which your committee is advised expresses the views of the court, follows:

APRIL 25, 1934.

HON. WILLIAM H. KING,
United States Senate, Washington, D.C.

MY DEAR SENATOR KING: I enclose the bill making the change of name in the Court of Appeals which Judge Van Orsdel and I spoke to you about this morning, and I wish again to thank you for your assurance that you would introduce it tomorrow morning and have it acted on by the Judiciary Committee to which you will have it referred next Monday. As the session will soon be over, the element of time is of great importance.

The sole purpose of the bill is to correct a misnomer in the title of the court. It creates no new office, adds no jurisdiction, and has no other purpose than that mentioned above, but this is an important purpose, and its lack of notice heretofore has been the cause of great misunderstanding on the part of the bar of the importance of the court and its part in the Federal judicial system. It is an appellate court for matters arising in the District of Columbia, just as the Supreme Court of Utah is for matters arising in Utah, but this is only a part of its jurisdiction and is the least part. Its national jurisdiction is broader than that of any other national court, except the Supreme Court of the United States. For instance, questions with no relation to the District of Columbia but entirely national in their scope are constantly arising. These involve the Transportation Act and the Interstate Commerce Act; mandamus proceedings in relation to Indian treaties; equity proceedings in relation to public lands; proceedings for the enforcement of the postal laws; suits against the Federal Power Commission; suits against the Civil Service Commission; suits against the Alien Property Custodian; suits against the Federal Trade Commission; title to patented public lands; appeals from the Board of Tax Appeals without relation to the residence of the taxpayer; proceedings under War Veterans' Act; proceedings in relation to irrigation projects; proceedings in relation to cancelation of mineral and oil leases; proceedings in relation to the admission of aliens; the enrollment of Indians; suits under the anti-trust laws; and appeals from the Radio Commission.

The Supreme Court in a number of cases has declared the court is a court of the United States. (See *Benson* v. *Henkle*, 198 U.S. 1; *James* v. *United States*, 202 U.S. 407, 408.) In the recent case of *O'Donoghue* v. *United States* (289 U.S. 516, 551), the Supreme Court said of the Court of Appeals: "It is a constitutional court of the United States." And in another part of the same opinion (p. 545) said of the Supreme Court and Court of Appeals of the District of Columbia: "We take the true rule to be that they are courts of the United States, vested generally with the same jurisdiction as that possessed by the interior Federal courts located elsewhere in respect of the cases enumerated in section 2 of article III." And in *Federal Trade Commission* v. *Klesner* (274 U.S. 145, 154), the Supreme Court said: "The courts of the District of Columbia are Federal courts of the United States." And in the same case (p. 156): "The parallelism between the Supreme Court of the District and the Court of Appeals of the District, on the one hand, and the district courts of the United States and the circuit courts of appeals on the other, * * * is complete." Many acts of Congress also refer to the courts as "courts of the United States."

If you will pardon a personal reference, Attorney General Mitchell told me, as an inducement to leave the United States District Court for Virginia to come to the Court of Appeals, that as a result of his 4 years as Solicitor General and his experiences as Attorney General he was of opinion that the Court of Appeals was, after the Supreme Court of the United States, the most important Federal court in the country. He was speaking, of course, from the viewpoint of its general Federal jurisdiction, and this of course grows out of its location at the seat of government.

The dignity of the court and its appeal to the highest grade lawyers in the country when vacancies occur make the correction of this misnomer important, and I very earnestly urge that you will take the matter under your consideration to the end that it may be accomplished before the session ends.

Finally, may I add this statement? This court disposes of more cases each year than any other Circuit Court of Appeals except the second (New York), and the court is now up to date with its docket and the time required for a hearing after the filing of the appeal is from 3 to 4 months, dependent upon the time required for printing records and filing briefs.

Yours very cordially,

D. LAWRENCE GRONER

[p. 2]

The Attorney General states that he has no objection to the proposed change of name. A communication received by the chairman of the committee from the Attorney General in this connection follows:

DEPARTMENT OF JUSTICE
Washington, D.C., May 7, 1934

HON. HATTON W. SUMNERS
Chairman Committee on the Judiciary, House of Representatives

MY DEAR MR. CHAIRMAN: I have your letter of May 3 in which you request my comment on H.R. 9437, a bill to change the name of the Court of Appeals of the District of Columbia to the United States Court of Appeals for the District of Columbia.

In reply I wish to say that I know of no objection to the proposed change.

Sincerely yours,

HOMER CUMMINGS, *Attorney General*

[p. 3]

1.9d (3) CONGRESSIONAL RECORD, VOL. 78 (1934)

1.9d (3) (a) May 10: Passed Senate, p. 8479

COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA

The Senate proceeded to consider the bill (S. 3524) to amend an act of Congress approved February 9, 1893, entitled "An act to establish a court of appeals for the District of Columbia, and for other purposes."

Mr. ROBINSON of Arkansas. The report states that the object in changing the name of this court?

Mr. KING. Mr. President, I was requested to introduce this bill by the judges of the court. It changes the name from the "Court of Appeals of the District of Columbia" to the "United States Court of Appeals for the District of Columbia."

Mr. ROBINSON of Arkansas. The report states that the present title "Court of Appeals of the District of Columbia" implies that the court is merely an appellate court for matters arising in the District of Columbia, whereas it exercises other jurisdiction.

Mr. KING. Exactly.

Mr. ROBINSON of Arkansas. I have no objection.

Mr. KING. Much of the business of the court comes now from outside the District, and therefore its duties are of a broader nature than implied by the name, "Court of Appeals of the District of Columbia."

The bill was ordered to be engrossed for a third reading, read the third time, and passed, as follows:

Be it enacted, etc., That the court established by the act of February 9, 1893 (27 Stat. 434), entitled "An act to establish a court of appeals for the District of Columbia, and for other purposes", shall hereafter be known as the United States Court of Appeals for the District of Columbia.

[p. 8479]

1.9d (3) (b) June 5: Passed House, pp. 10536–10537
[No Relevant Discussion on Pertinent Section]

1.9e COURT OF APPEALS REVIEW ACT
June 25, 1948, P.L. 80–773, §1254, 62 Stat. 928

§ 1254. Courts of appeals; certiorari; appeal; certified questions

Cases in the courts of appeals may be reviewed by the Supreme Court by the following methods:

(1) By the writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree;

(2) By appeal by a party relying on a State statute held by a court of appeals to be invalid as repugnant to the Constitution, treaties or laws of the United States, but such appeal shall preclude review by writ of certiorari at the instance of such appellant, and the review on appeal shall be restricted to the Federal questions presented;

(3) By certification at any time by a court of appeals of any question of law in any civil or criminal case as to which instructions are desired, and upon such certification the Supreme Court may give binding instructions or require the entire record to be sent up for decision of the entire matter in controversy.

[p. 928]

1.9e (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 308, 80th Cong., 1st Sess. (1947)

REVISION OF TITLE 28, UNITED STATES CODE

April 25, 1947.—Ordered to be printed

Mr. Robison, from the committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 3214]

The Committee on the Judiciary submits the following report in explanation of the bill (H.R. 3214) to revise, codify, and enact into law title 28 of the United States Code entitled "Judicial Code and Judiciary," and recommends that the bill do pass. The present bill has been substituted for an earlier bill (H.R. 2055) on which hearings were held and contains changes recommended by the subcommittee.

PRELIMINARY STATEMENT

SCOPE OF REVISION

The source material of this revision was the Judicial Code of 1911 constituting, in part, title 28 of the United States Code. To this were added appropriate sections from other titles which could be transferred without impairing the framework of the official United States Code prepared by the former Committee on Revision of the Laws of the House and enacted by Congress in 1926.

This revision includes all applicable laws in effect March 10, 1947.

Before actual revision was begun a scientific plan was assembled. This included:

1. The complete text of title 28, United States Code, 1940 edition, and the latest supplement thereto.
2. Pertinent provisions from other titles of the code.
3. Complete text of original acts set out in the Statutes at Large.
4. Applicable constructions by the courts.
5. Notes based upon a careful examination of the Code of Federal Regulations and law reviews.
6. Exhaustive historical notes.
7. Notes on the Rules of Civil Procedure and Rules of Criminal Procedure promulgated by the Supreme Court.

[p. 1]

8. Suggestions from the bench and bar.

Revision, as distinguished from codification, required the substitution of plain language for awkward terms, reconciliation of conflicting laws, repeal of superseded sections, and consolidation of related provisions.

HISTORY OF THE JUDICIAL CODE

The first law establishing the Federal courts and regulating their jurisdiction and procedure was enacted at the first session of the First Congress. This law of September 24, 1789 (ch. 21, 1 Stat. 73), is popularly known as the Judiciary Act of 1789.

This first judicial code was very brief. It comprised only 35 sections. But the Nation itself was small, with a population of only 3,000,000.

From the beginning the body of the law relating to the courts and judicial officers and their procedure developed gradually by unrelated acts, without any real effort to reconcile conflicting provisions of successive enactments. At the outbreak of the Civil War the Statutes at Large numbered 12 volumes. That war and the reconstruction period which followed gave impetus to Federal legislation.

The whole of the expanding body of Federal law was carefully examined by the commissioners empowered by Congress in 1866 to prepare the Revised Statutes of the United States. Obsolete and superseded provisions, which had accumulated during the 88-year period from 1789 to the date of the final approval of the Revised Statutes in 1877, were repealed. Inconsistent provisions were reconciled and all existing laws relating to the courts were analyzed, revised, and consolidated into title XIII, of the Revised Statutes, entitled "The Judiciary," comprising 21 chapters and 564 sections.

The Judicial Code of 1911 was enacted into law by act March 3, 1911 (ch. 231, 36 Stat. 1152), after long and exhaustive study by the same commission that drafted the Criminal Code of 1909.

In preparing the Judicial Code of 1911 the commissioners discarded the analysis and arrangement used in the Revised Statutes. Statutes were revised and consolidated, obsolete laws were repealed and improvements were introduced. The old circuit courts were abolished and their jurisdiction transferred to the district courts.

Thirty-six years have passed since the enactment of the Judicial Code of 1911. That is a longer time than elapsed between the revisions of 1878 and 1911. It comprises a period which witnessed unprecedented changes on the national scene. During those years the population of the United States leaped from 91,000,000 to 140,000,000 and the Nation twice experienced the tremendous social changes that accompany world wars. It is a tribute to Congress and to the draftsmen of the Judicial Code of 1911 that our judicial system has withstood the impact of these terrific changes. However, there is little doubt that the changes of the past 36 years make imperative this revision of the Judicial Code. [p. 2]

SECTION 1254—SECTION REVISED

Based on title 28, U.S.C., 1940 ed., §§346 and 347 (Mar. 3, 1911, ch. 231, §§239, 240, 36 Stat. 1157; Feb. 13, 1925, ch. 229, §1, 43 Stat. 938; Jan. 31, 1928, ch. 14, §1, 45 Stat. 54; June 7, 1934, ch. 426, 48 Stat. 926).

Section consolidates sections 346 and 347 of title 28, U.S.C., 1940 ed.

Words "or in the United States Court of Appeals for the District of Columbia" and "or of the United States Court of Appeals for the District of Columbia" in sections 346 and 347 of title 28, U.S.C., 1940 ed., were omitted. (See section 41 of this title.)

The prefatory words of this section preceding paragraph (1) were substituted for subsection (c) of said section 347.

The revised section omits the words of section 347 of title 28, U.S.C., 1940 ed., "and with like effect as if the case had been brought there with unrestricted appeal", and the words of section 346 of such title "in the same manner as if it had been brought there by appeal". The effect of subsections (1) and (3) of the revised section is to preserve existing law and retain the power of unrestricted review of cases certified or brought up on certiorari. Only in subsection (2) is review restricted.

Changes were made in phraseology and arrangement.

[p. A107]

1.9e (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 1559, 80th Cong., 2d Sess. (1948)

REVISING, CODIFYING, AND ENACTING INTO LAW TITLE 28 OF THE UNTED STATES CODE, ENTITLED "JUDICIAL CODE AND JUDICIARY"

JUNE 9 (legislative day, JUNE 1), 1948.—Ordered to be printed

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Mr. WILEY, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 3214]

The Committee on the Judiciary, to whom was referred the bill (H.R. 3214) to revise, codify, and enact into law title 28 of the

United States Code, entitled "Judicial Code and Judiciary," having considered the same, do now report the bill to the Senate favorably, with amendments, and recommend that the bill, as amended, do pass.

The purpose of the bill is to codify and revise the laws relating to the Federal judiciary and judicial procedure.

No revision of these laws has been made since 1911, and the Judicial Code enacted in that year did not include all the laws upon the subject.

A tremendous amount of additional legislation in this field has been enacted since 1911. Consequently, there is now a great mass of statutory material upon this subject, much of which is archaic, ambiguous, conflicting, and to an unascertained extent repealed by implication by later statutes. These statutes are scattered through many volumes of the Statutes at Large which are not easily accessible to the bench and bar. Moreover, many of the statutes relating to procedure appearing in the books have been rendered wholly obsolete by the Federal Rules of Civil Procedure prescribed by the Supreme Court. This situation results in the loss of much time and effort on the part of the bench and bar in determining what is the present law in this field, always at the risk of possible error.

It is evident, therefore, that a thorough codification and revision of the statutes relating to the judiciary and its procedure is very much in the public interest in order that the law in this important field may be clear, certain, and readily available.

The bill H.R. 3214 accomplishes these desirable results. The statutory material presently in force has been arranged in the bill in a logical and consistent way, rendering it easily ascertainable. [p. 1] Existing inconsistencies and ambiguities have been removed and obsolete and archaic provisions eliminated or modernized.

By enacting this bill into positive law as title 28 of the United States Code, that title will thereby become the law rather than merely presumptive evidence of the law, and reference to prior volumes of the Statutes at Large will be rendered wholly unnecessary.

Many noncontroversial improvements have been effected which, while individually small in themselves, add up to a very substantial improvement in and modernization of the law relating to the Federal judiciary. At the same time great care has been exercised to make no changes in the existing law which would not meet with substantially unanimous approval.

The bill with the amendments proposed by the committee includes all pertinent laws to January 5, 1948, and the bill provides for it to become effective September 1, 1948, thus allowing an interval in which the bench and bar may become acquainted with the revised arrangement of the law.

The report of the Committee on the Judiciary of the House of Representatives upon the bill (H. Rept. No. 308, 80th Cong., 1st sess.) describes in detail the scope of the revision, the manner in which it was carried out by the House Committee on the Judiciary and its predecessor, the House Committee on Revision of the Laws, and the principal improvements effected. Appended to the report are the revisers' notes to each section, together with accompanying tables. These explain in great detail the source of the law and the changes made in the course of the codification and revision.

As passed by the House of Representatives, the bill included provisions covering the Tax Court of the United States. These proposed to transfer that court from the Internal Revenue Code, title 26, United States Code, to the Judicial Code. This proposed transfer of the Tax Court to the Judicial Code has proved controversial with respect to the court and as to those who are entitled to practice before it. Since every effort has been made to avoid controversial matters in this revision, the committee recommends that all Tax Court provisions be omitted from this bill.

One of the changes proposed by the House of Representatives with respect to the Tax Court provided that Tax Court decisions should be reviewable on appeal to the same extent as similar decisions of the district courts. This in effect repeals the contrary rule laid down in *Dobson* v. *Commissioner of Internal Revenue* (320 U. S. 489). This proposal met with unanimous approval at the hearings on the bill held by your committee. It is recommended that the House amendment be retained. In view of the elimination of the Tax Court from the bill, this must be accomplished by an amendment of the Internal Revenue Code. Such an amendment is included among the committee amendments.

The amendments proposed by the committee, together with the reasons for each, are listed below.

* * * * * * *

[p. 2]

1.9e (3) CONGRESSIONAL RECORD

1.9e (3) (a) VOL. 93 (1947), July 7: Passed House, p. 8392

[No Relevant Discussion on Pertinent Section]

1.9e (3) (b) VOL. 94 (1948), June 12: Amended and passed Senate, p. 7927

[No Relevant Discussion on Pertinent Section]

1.9e (3) (c) VOL. 94 (1948), June 16: House concurs in Senate amendments, p. 8501

[No Relevant Discussion on Pertinent Section]

1.10 ADULTERATED FOOD, AS AMENDED

21 U.S.C. §342(a)

[Referred to in 21 U.S.C. §§346, 346a (a), 348(a) (2)]

ADULTERATED FOOD

§ 342

A food shall be deemed to be adulterated—

Poisonous, insanitary, etc., ingredients

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a (a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

June 25, 1938, c. 675, § 402, 52 Stat. 1046; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Mar. 16, 1950, c. 61, § 3(d), 64 Stat. 21; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. April 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 22, 1954, c. 559, § 2, 68 Stat. 511; July 9, 1956, c. 530, 70 Stat. 512; Sept. 6, 1958, Pub.L. 85–929, § 3(a), (b), 72 Stat. 1784; Mar. 17, 1959, Pub.L. 86–2, 73 Stat. 3, July 12, 1960, Pub.L. 86–618, Title I, §§ 102(a) (1), (2), 105(c), 74 Stat. 397, 404; and amended June 29, 1966, Pub.L. 89–477, 80 Stat. 231; July 13, 1968, Pub.L. 90–399, § 104, 82 Stat. 352.

1.10a FEDERAL FOOD, DRUG, AND COSMETIC ACT

June 25, 1938, P.L. 75–717, §402, 52 Stat. 1046

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or dele-

terious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or [p. 1046] make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: ***Provided,*** **That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.**

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: ***Provided,*** **That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.**

[p. 1047]

1.10a (1) SENATE COMMITTEE ON COMMERCE

S. REP. No. 91, 75th Cong., 1st Sess. (1937)

FOOD, DRUGS, AND COSMETICS

FEBRUARY 15, 1937.—Ordered to be printed

Mr. COPELAND, from the Committee on Commerce, submitted the following

REPORT

[To accompany S. 5]

The Committee on Commerce, to whom was referred the bill (S. 5) to prevent the adulteration, misbranding, and false advertisement of food, drugs, devices, and cosmetics, in interstate, foreign, and other commerce subject to the jurisdiction of the United

States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, having considered the same, report thereon with certain amendments, and as so amended, recommend that the bill do pass. The amendments are incorporated in the bill as reported.

This bill has been prepared with three basic principles in mind: First, it must not weaken the existing laws; second, it must strengthen and extend the law's protection of the consumer; and, third, it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest.

This bill meets these three principles. It has been prepared after many and extensive conferences with the enforcement agencies of the Government and with representatives of various consumer groups or associations, professional groups, and the industries to be regulated.

Separately called meetings were held with representatives of the food, drug, and cosmetic industries. Letters inviting suggestions were sent to many persons known to be interested in the subject. Several volumes of suggestions have been received from persons in the groups just mentioned. These suggestions have been carefully studied; many of them rejected; some accepted; some accepted in part or in effect. The hearings which have been held by committees of the Senate and House of Representatives on previous bills in former sessions of the Congress have been reviewed and studied to take advantage of the information and discussions contained in them.

[p. 1]

The legislative effort to secure a better law on this subject began in June 1933, with the introduction of S. 1944. Since that time there have been many bills and many revisions of bills. There have been numerous hearings by committees of the Congress. The subject has been debated on the floors of Congress, in the press, throughout the industries, and by the public. This study has gone on over a period of 3½ years. In the preparation of the present bill there has been an earnest, painstaking effort to take advantage of what light has been shed from these various courses.

This bill is presented with the confident assurance that, insofar as it is possible, all the known facts have been utilized, and that the measure is capable of accomplishing the purposes declared for it. And it is a fair bill which will enable honest business to be carried on without interference, except such as is necessary to safeguard the public health.

It must be realized that the preparation of a bill which affects so many and such varied industrial interests in intricate and technical particulars, and which concerns and appeals to so many, including consumers and others not immediately in the businesses affected, necessarily presents a task of almost indescribable difficulty. It is only natural that many emphasize their immediate concerns without proportionate regard to the rights of others in matters which do not directly interest them. Many advance their particular interests without consideration for the technical and legal requirements that are presented in the preparation of a bill.

Conflict also develops in the clash of extreme positions. There are some who would give no regard whatever to the fairness of the bill's application to business. Unforunately, there are some who give no regard, or very little, to the effectiveness of the bill for protection of the consumer. It should be said with emphasis that all business does not fall in that latter class. Business has not been unsympathetic to the effort for a better law. Strong support for a better law exists in the industries affected.

Considering the variety and diversity of interest, the unavoidable controversies that honestly arise among these interests, a so-called "perfect" bill hardly can be formulated. This bill is not a thing of perfection. It simply represents an earnest effort to serve its declared purposes. It is introduced in the hope that all who desire to see its purposes accomplished and all who are friends of the movement for a better law, will give it unbiased, impartial, and careful consideration, and, after so doing, will see their way clear to support and advocate its enactment.

It will be noted that the sequence has been changed from that of previous bills. This has been done with a view to making it simpler to read, both while it is a bill and later as a law, when it will be constantly examined by enforcement officials, courts, and lawyers. It was thought that it would be an advantage to have the prohibited acts and the enforcement machinery put in the forepart of the bill so that one may quickly learn those requirements, and then move deeper into the bill for details on the particular problem in which he is interested.

The bill has been made shorter and less verbose than previous bills. That has been done without deleting any effective provisions. [p. 2] It has been done by avoiding unnecessary repetitions which existed in previous bills, and by consolidating at a single place in a few lines what appeared heretofore at several different places.

That was also accomplished by eliminating some provisions which, while lending nothing to the strength of the bill, presented the possibility of confusion in enforcement and perhaps raised the issue of its constitutionality. For instance, the requirement that claims for drug products should be supported by medical opinion was deleted. Great difficulty always has been found in defining "medical opinion". In one State, certain practitioners are licensed and their opinions would be considered medical opinion, whereas in another State such practitioners would not be licensed. Furthermore, as shown, in the previous discussions, it would often be impossible to determine what the state of medical opinion is on controverted subjects.

When those considerations were added to the possibility that the guilty might escape through the uncertainties of such a provision, and the strong likelihood that courts would invalidate a statute making medical opinion the criterion of truth and the gage of a criminal offense, the provision was deleted. The bill is stronger for the deletion. Medical testimony can and will be adduced in enforcing the law. It will be received as evidence. But, the bill will avoid the danger of making it a legal standard, usually undeterminable, the violation of which incurs criminal penalties.

The bill also includes a provision that a drug shall be deemed to be misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration, prescribed or recommended in the labeling or advertising thereof. That provision has been in previous bills.

The controversial subject of control of advertising has been met by providing for the prohibition of false advertising by injunction. The bill also states differently the offense of false advertisement. Previous bills have defined false advertisements as those which are "false or misleading in any particular". That definition has occasioned no end of controversy—some of it quite meritorious—on the ground that when applied to the unlimited field of advertising it was too elastic and encompassed things far beyond the purposes of the bill. Also, it would lend itself to unnecessary and unjustified governmental interference in the affairs of business, and impose upon the Government a job far beyond the Government's financial and personnel capacities to enforce. The statement of the offense in the bill defines those subjects pertaining to food, drugs, and cosmetics which should be under Government control.

There has been controversy as to whether the Food and Drug Administration or the Federal Trade Commission should enforce the bill's provisions on advertising. On the premise that advertisements of foods, drugs, and cosmetics are nothing more than extensions of the labeling, this bill proposes that the control be vested in the Food and Drug Administration which enforces the provisions on adulteration and labeling. But, it does not have the effect of depriving the Federal Trade Commission of its jurisdiction to proceed against false advertising in such form as to make it an unfair method of competition. The bill specifically provides that it shall not be construed as impairing or diminishing the powers of the Federal Trade Commission.

[p. 3]

The bill simply provides that the district courts of the United States shall have the power to grant temporary and permanent injunctions against the dissemination of any advertisement which contains—

> any representation regarding any food, drug, device, or cosmetic, or the ingredients thereof, or the substances therein, or the identity, strength, quality, purity, quantity, origin, source, harmlessness, or safety thereof, or the nutritional, dietary, curative, therapeutic, preventive, diagnostic, or beneficial effects thereof, or the safety or efficiency of the dosage, frequency, or duration of use pertaining thereto, which is false or misleading in any material particular.

It is submitted that that is a perfectly proper power to vest in the district courts of the United States, and that it not only is proper, but necessary, that the Food and Drug Administration which has foods, drugs, and cosmetics under observation, shall be authorized to seek such injunctions at the hands of the courts. No one can dispute that such advertisements should be enjoined. The fact that the Federal Trade Commission may proceed against advertisers using unfair methods of competition should not prevent the grant to the Food and Drug Administration of this additional, necessary, and very desirable power to protect the public against advertisements which bear directly on public health.

The provisions of the previous bills with respect to seizure also have been subject to much controversy. Again, it has been attempted to take advantage of what has been learned in previous studies. This bill permits multiple seizures of any food, drug, device, or cosmetic that is adulterated. It permits multiple seizures for misbranding when the misbranding has been the basis of a prior judgment in favor of the Government, or when the Secretary of Agriculture has probable cause to believe, from facts found by him, that the misbranding renders the article dangerous to health.

The only limitation is that misbranding which does not render an article dangerous to health, shall not be handled by multiple seizures made at the will of enforcement officers. That has been the declared policy of the Food and Drug Administration in enforcing the existing law. The bill therefore does no more than write into the law what is declared to be the policy of the Administration. But it is important that that policy be written into the bill because it is the proper policy, and because succeeding administrations should be held to that policy.

There is no comparison between this bill and the existing law as to the extent of their respective applications and the extent of the enforcement officers' powers under them. Where the existing law is entirely negative in its labeling requirements, this bill is affirmative. Where the existing law limits its attacks against misbranding on therapeutic matters to statements which are false and fraudulent, this bill expands them to those which are false or misleading.

Technical, innocent violations of this bill will frequently arise. Overzealous enforcement officers could cause honest business untold damage and annoyance. The bill, therefore, limits the enforcement officers in the drastic power of unlimited seizure to cases of adulteration and those cases of misbranding where, in the public interest, the power should be exercised. In addition, this bill increases the criminal penalties for adulteration and misbranding over those in the existing law, and adds injunction, temporary and permanent, as a means of prohibiting adulteration and misbranding. The existing law does not have such a provision.

[p. 4]

The only other change of consequence in the seizure provision is that when seizures have been made the trial may be held in a district of reasonable proximity to the claimant's place of business. Nothing is claimed for this provision except that it is fair. Goods must be seized wherever found. But, there is no reason why a claimant for the goods, who perhaps may reside across the continent, should be compelled to cross the country to try the case.

A summary of the principal respects in which this bill increases the scope of the old law and affords the public greater protection follows:

ADVERTISING

1. Prohibits false advertising of food, drugs, therapeutic devices, and cosmetics.

FOODS

2. Provides for the promulgation of standards of identity and a reasonable standard of quality for food. (A standard of quality is authorized by the present law for canned food only.)

3. Requires the labeling of unstandardized food to disclose the ingredients by name.

4. Prohibits traffic in food which is dangerous to health. (The present law permits regulation of dangerous food only in the event that the poison is added.)

5. Prohibits addition of poison. If it cannot be avoided in pro-

duction or manufacture, when it reaches the consumer the product must be safe for human use.

6. Eliminates the "distinctive name" proviso of the existing law under which the sale of products, the labels of which are misleading, are now permitted sale.

7. Requires fully informative labeling of infant and invalid food.

8. Requires label declaration of artificial colors and artificial flavors in food.

9. Forbids traffic in confectionery containing metallic trinkets and other inedible substances which have been found to be a menace to the welfare of children.

10. Authorizes emergency license control of food that might be dangerous by reason of contamination with micro-organisms. Such licensing is limited to operations in which the public health cannot be protected otherwise.

COSMETICS

11. For the first time places cosmetics under Federal supervision. Requiring cosmetics to be truthfully sold and outlaws those injurious to health.

DRUGS

12. Prohibits traffic in drugs and devices which are dangerous to health under the conditions of use prescribed in the labeling or advertising.

13. Requires habit-forming drugs to bear warning labels.

14. Requires adequate directions for use of drugs and devices and appropriate warnings against their probable misuse through overdosage, or by children, or in disease conditions where they may be dangerous.

[p. 5]

15. Sets up special protection to consumers against drugs liable to deterioration.

16. Requires that claims of effect of drugs and devices must not be false or misleading in any material particular. (The present law makes fraud, that is, wilful intent to deceive, an element of the offense; unwarranted therapeutic claims resulting from sheer ignorance of the manufacturer are not actionable.)

17. Defines "nonofficial" drugs as illegal if the standard of strength varies from the standard claimed. (The present law prescribes only those which fall below the standard claimed. Drugs which are too strong may be quite dangerous.)

18. Requires that antiseptics possess germicidal power.

19. Requires declaration on the label of the names of active ingredients of nonofficial drugs.

GENERAL

20. Prohibits the use of poisonous containers for food, drugs, and cosmetics.

21. Requires that food, drugs, and cosmetics be prepared and handled under conditions of reasonable cleanliness.

22. Forbids the use of uncertified and impure coal-tar colors in food, drugs, and cosmetics.

23. Prohibits slack-filling and the use of deceptive containers for food and drugs.

24. Provides for factory inspection and the procurement of records needed to prove Federal jurisdiction.

25. Provides increased penalties for violations.

26. Authorizes the Federal courts to enjoin violations.

[p. 6]

1.10a (2) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 2139, 75th Cong., 3rd Sess. (1938)

FOOD, DRUG, AND COSMETIC ACT

APRIL 14, 1938.—Committed to the Committee of the Whole House on the state of the Union and ordered to be printed

Mr. LEA, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany S. 5]

The Committee on Interstate and Foreign Commerce, to whom was referred the act (S. 5) to prevent the adulteration, misbranding and false advertising of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, report favorably thereon with an amendment and recommend that the act do pass.

The committee amendment strikes out all of the Senate bill and inserts in lieu thereof a substitute which appears in the reported bill in italic type.

The act herewith reported is the culmination of more than 5 years of study by your committee.

GENERAL PURPOSES

This act seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906, as amended (U.S.C., title 21, secs. 1–15). That act is popularly known as the Wiley pure-food law, because that great pioneer in pure food and drug legislation, Dr. Harvey W. Wiley, led the fight for its enactment.

While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. [p. 1]

Sections 402 and 403 define, respectively, adulterated food and misbranded food. They contain new provisions not found in the old law but the need for which has been very definitely demonstrated [p. 5] through enforcement proceedings under the old law. Primarily these new provisions provide control against unsanitary and contaminated foods, foods packed in poisonous containers, various forms of food debasement, and provide for more informative labeling of foods. [p. 6]

1.10a (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 2716, 75th Cong., 3rd Sess. (1938)

FOOD, DRUG, AND COSMETIC ACT

JUNE 11, 1938.—Ordered to be printed

Mr. LEA, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 5]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 5) to prevent the adulteration, misbranding, and false advertisement of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

Chapter I—Short Title

Section 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

Chapter II—Definitions

* * * * * * *

[p. 1]

Chapter IV—Food

* * * * * * *

Adulterated Food

Sec. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decom- [p. 7] *posed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.*

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: Provided, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and

such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

[p. 8]

1.10a (4) CONGRESSIONAL RECORD

1.10a (4) (a) VOL. 81 (1937), March 9: Amended and passed Senate, p. 2009

The PRESIDING OFFICER. The next amendment will be stated.

The next amendment of the Committee on Commerce was under the subtitle "Adulterated food", in section 11, paragraph (a), on page 20, line 7, after the word "section", to strike out "15, or in excess of the limits of tolerance prescribed by regulations as provided by section", so as to make the paragraph read:

ADULTERATED FOOD

SEC. 11. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance which may render it injurious to health, or which is unsafe within the meaning of section 15; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

The amendment was agreed to.

The next amendment was, in the same section, paragraph (b), on page 21, line 1, after the word "strength", to strike out "to" and insert "or", so as to make the paragraph read:

(b) (1) If any valuable constituent has been in whole or in part abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

The amendment was agreed to.

[p. 2009]

1.10a (4) (b) VOL. 83 (1938), June 1: Amended and passed House, pp. 7903

[No Relevant Discussion on Pertinent Section]

1.10a (4) (c) VOL. 83 (1938), June 10: Senate agrees to conference report, p. 8733

"ADULTERATED FOOD

"SEC. 402. A food shall be deemed to be adulterated—

"(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

"(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

"(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided,* That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

"(d) If it is confectionery, and, it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of 4/10 of 1 per centum, natural gum, and pectin: *Provided,* That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

[p. 8733]

1.10a (4) (d) VOL. 83 (1938), June 13: House agrees to conference report, pp. 9089–9090

[No Relevant Discussion on Pertinent Section]

1.10b FEDERAL ADULTERATED FOOD AMENDMENTS

July 22, 1954, P.L. 83–518, §2, 68 Stat. 511

SEC. 2. Clause (2) of section 402 (a) of the Federal Food, Drug, and Cosmetic Act is amended to read as follows: "(2) if it bears or contains any added poisonous or added deleterious substance, except a pesticide chemical in or on a raw agricultural commodity,

which is unsafe within the meaning of section 406, or if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a);".

[p. 511]

1.10b (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 1385, 83rd Cong., 2d Sess. (1954)

AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO RESIDUES OF PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

MARCH 23, 1954.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. SPRINGER, from the U. S. Congress House Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 7125]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 7125) to amend the Federal Food, Drug, and Cosmetic Act with respect to residues of pesticide chemicals in or on raw agricultural commodities, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are as follows:

Page 4, line 10, strike out "(1)" and insert "(l)".

Page 5, line 8, after "from", insert "the requirement of".

Page 6, line 7, strike out "(1)" and insert "(l)".

Page 6, line 9, after "Secretary", insert "of Health, Education, and Welfare."

Page 6, line 20, strike out "event" and insert "events".

Page 6, line 25, strike out "(1)" and insert "(l)".

Page 7, line 2, after "or", insert "in the event"; and, in lines 3 and 4, after "Secretary", insert "of Health, Education, and Welfare".

Page 10, line 1, strike out "person," and insert "person".

Page 11, line 3, strike out "or" and insert "of".

Page 12, line 20, strike out "(1)" and insert "(l)".

Page 13, line 17, strike out "(1)" and insert "(l)".

All of the foregoing amendments are either clerical or for the purpose of making minor clarifications.

PURPOSE

The primary purpose of the bill is to assure greater protection of the public health by improving, simplifying, and speeding up the [p. 1] method for regulating, under the provisions of the Federal Food, Drug, and Cosmetic Act, the amount of residue which may remain on raw agricultural commodities after use of pesticide chemicals. Pesticide chemicals are substances such as insecticides, fungicides, and weedkillers used in the production, storage, and transportation of food for the purpose of controlling insects, plant diseases, weeds, and other pests. This bill is an exercise of the power of Congress over the regulation of interstate commerce in adulterated food.

This bill would accomplish its purpose primarily by adding to the Federal Food, Drug, and Cosmetic Act an improved procedure for establishment of tolerances for pesticide chemicals remaining in or on raw agricultural commodities. Poisonous or deleterious substances intentionally added to, or which remain in, other food are subject to existing law and would not be affected by this bill.

A primary objective in drafting the bill was to develop legislation that would provide for prompt administrative action to permit effective use of pesticide chemicals without hazard to the public health; legislation that would be safe for consumers and practical for producers.

The committee knows of no opposition to the bill. All interested parties are agreed as to the need for the bill.

Existing law

Under existing law, added poisonous and deleterious substances—and most pesticide chemicals fall in this class—must be kept out of foods unless they are required in production or cannot be avoided by good manufacturing practice. When such a substance is required in production—as many pesticide chemicals are required in growing agricultural crops—a tolerance may be established by the Secretary of Health, Education, and Welfare, but only after a formal public hearing. (The maximum amount of residue that may lawfully remain in or on the food is commonly referred to as a tolerance.) Detailed findings of fact and conclusions must be made by the Secretary as to the required use of the pesticide and the residue levels that may safely be tolerated.

Need for new legislation

Regulations limiting the amount of pesticidal residue which may remain in or on food have been issued under the present law in only one instance, although the law authorizing such regulations has been in effect for over 15 years. During all that time control has been exercised through unofficial and informal tolerances. In 1950, lengthy public hearings were held for the purpose of establishing official tolerances (the maximum amount of poisonous or deleterious residue which may legally remain in or on food) for fresh fruits and vegetables. These hearings, at a cost of nearly a half-million dollars to Government, to industry, to agricultural organizations, and to the various land-grant colleges, produced a very large volume of evidence that had not theretofore been gathered together, but the record is still under consideration by the Government and the necessary tolerances have not yet been issued. This has been responsible for uncertainty under the law. It has handicapped the Government in enforcing the law, the grower in complying with the law, and the pesticide manufacturer and Federal and State agencies in discharging their responsibility for advising and making recommendations to the grower with [p. 2] respect to the use of pesticide chemicals. This, together with the introduction of a large number of new pesticide chemicals, some of which are known to be toxic, has been responsible for concern that existing law is inadequate to protect the public health.

It has been generally recognized that a primary reason why tolerances have not been established to control agricultural usage of pesticide chemicals as intended by Congress has been the cumbersome, time-consuming, and impracticable procedure prescribed by existing law.

SUMMARY OF THE BILL

Under this bill, a regulation establishing a tolerance for a pesticide chemical used on raw agricultural commodities may be initiated by an applicant for registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act or by the Secretary of Health, Education, and Welfare. It is anticipated that, in the usual case, registration of a new economic poison would be withheld by the Department of Agriculture pending the issuance of the tolerance.

The tolerance-setting process for a particular pesticide chemical started by a person other than the Secretary is accomplished by *(a)* filing with the Secretary of Agriculture a request to certify to the Secretary of Health, Education, and Welfare that the pesticide chemical is useful for its intended purpose and that the requested tolerance reflects the amount of residue, if any, likely to result when the pesticide is used as proposed; and *(b)* filing of a petition proposing the tolerance, together with supporting scientific data to establish safe residue levels, with the Secretary of Health, Education, and Welfare. Within 90 days after the Secretary of Agriculture has certified to usefulness, the Secretary of Health, Education, and Welfare would make public a regulation establishing the tolerance.

The basic authority, under the bill, to establish tolerances or exemptions from tolerances directs the Secretary of Health, Education, and Welfare to limit in or on raw agricultural commodities residues of poisonous or deleterious pesticide chemicals and pesticide chemicals of unknown or uncertain toxicity "to the extent necessary to protect the public health." In doing so, the Secretary is directed to take into account the necessity for the production of an adequate, wholesome, and economical food supply and the Secretary of Agriculture's opinion as to the amount of residue that will remain, as well as the overall effect the pesticide chemical may have in consumers' diets.

The Secretary is authorized to fix the tolerance at zero—and thus prohibit any residue—when the scientific data submitted does not justify a greater tolerance.

Provision is made for the referral of a petition proposing a tolerance or exemption to an ad hoc advisory committee of scientific experts selected by the National Academy of Sciences for a report and recommendation where this is requested by the proponent of the tolerance or is otherwise deemed necessary by the Secretary of Health, Education, and Welfare. Such referral extends the time limits otherwise prescribed for administrative action. The report and recommendation of any such advisory committee is considered by the Secretary before a tolerance is established and may be made a part of the official record in the event of a public hearing, in accordance with the provisions of the Administrative Procedure Act.

[p. 3]

Section 2

The Federal Food, Drug, and Cosmetic Act (in sec. 301(a)) prohibits the shipment in interstate commerce of adulterated food.

Under section 402 (a) (2), a food is deemed to be adulterated if it bears or contains any "added" poisonous or deleterious substance which is "unsafe" within the meaning of section 406 of the act. Section 406 contains a general declaration that any poisonous or deleterious substance added to food is unsafe except where the substance is "required in the production thereof and cannot be avoided by good manufacturing practice." However, in any case where such a substance is so required or cannot be so avoided (and this is so in case of the use of pesticide chemicals in the production of most raw agricultural commodities), section 406 directs the Secretary of Health, Education, and Welfare to promulgate regulations limiting the quantity on the food to such extent as such Secretary finds to be necessary for protection of the public health.

As explained elsewhere in this report, the primary purpose of this legislation is to provide a new method, and new procedures, for regulating the amount of pesticide chemical residue which shall be permitted to remain in or on raw agricultural commodities.

To attain this objective, section 2 of the bill amends section 402 (a) (2) so as to provide, in the case of any raw agricultural commodity bearing or containing a pesticide chemical, that such commodity shall be deemed to be adulterated if such pesticide chemical is unsafe within the meaning of the new section 408 (a) which is being added to the law by section 3 of the bill. Thus, section 406 of the law will no longer be applicable in the case of raw agricultural commodities bearing or containing pesticide chemicals.

[p. 7]

1.10b (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 1635, 83rd Cong., 2d Sess. (1954)

AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO RESIDUES OF PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

JUNE 25 (legislative day, JUNE 22), 1954.—Ordered to be printed

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Mr. PURTELL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H.R. 7125]

The Committee on Labor and Public Welfare, to whom was referred the bill (H.R. 7125) to amend the Federal Food, Drug, and Cosmetic Act with respect to residues of pesticide chemicals in or on raw agricultural commodities, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

On page 18, line 20, immediately preceding section 4, add a new subsection (o) as follows:

(o) The Secretary of Health, Education, and Welfare shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) the acceptance of filing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d) (5); or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i) (2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection.

PURPOSE OF THE BILL

The primary purpose of the bill is to assure greater protection of the public health by improving, simplifying, and speeding up the procedure under the Federal Food, Drug, and Cosmetic Act, for [p. 1] regulating the amount of residue which may remain on raw agricultural commodities after use of pesticide chemicals.

Pesticide chemicals are substances such as insecticides, fungicides, and weedkillers used in the production, storage, and transportation of food for the purpose of controlling insects, plant diseases, weeds, and other pests.

A primary objective in drafting the bill was to develop legislation that would provide for prompt administrative action to permit effective use of pesticide chemicals without hazard to the public health; legislation that would be safe for consumers and practical for producers.

The committee knows of no opposition to the bill. All interested parties are agreed as to the need for the bill.

Existing law

Under existing law, added poisonous and deleterious substances —and most pesticide chemicals fall in this class—must be kept out of foods unless they are required in production or cannot be avoided by good manufacturing practice. When such a substance is required in production—as many pesticide chemicals are required in growing agricultural crops—a tolerance may be established by the Secretary of Health, Education, and Welfare, but only after a formal public hearing. Detailed findings of fact and conclusions must be made by the Secretary as to the required use of the pesticide and the residue levels that may safely be tolerated.

Need for new legislation

Regulations limiting the amount of pesticidal residue which may remain in or on food have been issued under the present law in only one instance, although the law authorizing such regulations has been in effect for over 15 years. During all that time control has been exercised through unofficial and informal tolerances. In 1950, lengthy public hearings were held for the purpose of establishing official tolerances for fresh fruits and vegetables. These hearings, at a cost of nearly a half-million dollars to Government, to industry, to agricultural organizations, and to the various land-grant colleges, produced a very large volume of evidence that had not theretofore been gathered together, but the record is still under consideration by the Government and the necessary tolerances have not yet been issued. This has been responsible for uncertainty under the law. It has handicapped the Government in enforcing the law, the grower in complying with the law, and the pesticide manufacturer and Federal and State agencies in discharging their responsibility for advising and making recommendations to the grower with respect to the use of pesticide chemicals. This, together with the introduction of a large number of new pesticide chemicals, some of which are known to be toxic, has been responsible for concern that existing law is inadequate to protect the public health.

It has been generally recognized that a primary reason why tolerances have not been established to control agricultural usage of pesticide chemicals as intended by Congress has been the cumbersome, time-consuming, and impracticable procedure prescribed by existing law.

[p. 2]

ANALYSIS OF THE BILL BY SECTIONS

An explanation of the various provisions of the bill is contained in the sectional analysis which follows:

* * * * * * *

Section 2

The Federal Food, Drug, and Cosmetic Act (in sec. 301 (a)) prohibits the shipment in interstate commerce of adulterated food.

Under section 402 (a) (2), a food is deemed to be adulterated if it bears or contains any "added" poisonous or deleterious substance which is "unsafe" within the meaning of section 406 of the act.

[p. 6]

Section 406 contains a general declaration that any poisonous or deleterious substance added to food is unsafe except where the substance is "required in the production thereof and cannot be avoided by good manufacturing practice." However, in any case where such a substance is so required or cannot be so avoided (and this is so in case of the use of pesticide chemicals in the production of most raw agricultural commodities), section 406 directs the Secretary of Health, Education, and Welfare to promulgate regulations limiting the quantity on the food to such extent as such Secretary finds to be necessary for protection of the public health.

As explained elsewhere in this report, the primary purpose of this legislation is to provide a new method, and new procedures, for regulating the amount of pesticide chemical residue which shall be permitted to remain in or on raw agricultural commodities.

To attain this objective, section 2 of the bill amends section 402 (a) (2) so as to provide, in the case of any raw agricultural commodity bearing or containing a pesticide chemical, that such commodity shall be deemed to be adulterated if such pesticide chemical is unsafe within the meaning of the new section 408 (a), which is being added to the law be section 3 of the bill. Thus, section 406 of the law will no longer be applicable in the case of raw agricultural commodities bearing or containing pesticide chemicals.

[p. 7]

1.10b (3) CONGRESSIONAL RECORD, VOL. 100 (1954)

1.10b (3) (a) April 5: Amended and passed House, pp. 4604

[No Relevant Discussion on Pertinent Section]

1.10b (3) (b) July 6: Amended and passed Senate, p. 9726

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

Mr. HOLLAND. Mr. President, I think this is an excellent bill, but I think the RECORD should contain the showing, which I believe is a good showing, contained in the committee report on the bill, indicating the improvements over existing law. I ask that that part of the report, including all of page 4 and down through the second paragraph on page 5, under the heading "Improvements Over Existing Law" be printed in the RECORD at this point as a part of my remarks.

There being no objection, the excerpt was ordered to be printed in the RECORD, as follows:

IMPROVEMENTS OVER EXISTING LAW

The principal respects in which this bill would change and improve existing law are—

1. A specific method for controlling the residue of pesticide chemicals which may remain in or on raw agricultural commodities is set up which is distinct from that controlling other poisonous or deleterious substances which are used in, or remain in, processed, fabricated, and manufactured food. In this way, recognition is given to the peculiar economic, agricul-

tural, and public health problems which are important in the regulation of pesticide chemicals. Unlike many other chemicals, pesticide chemicals are necessary instruments of agriculture in producing and expanding our food supply and are comprehensively regulated by the Department of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act.

2. The determination of questions of agricultural usefulness and probable residue levels involved in the establishment of tolerances, is made a function of the Department of Agriculture; while the determination of questions of a public health nature remains a function of the Department of Health, Education, and Welfare. In this way, a more logical grouping of governmental functions is effected than under existing law which casts the responsibility for determining agricultural questions as well as public health questions upon the Department of Health, Education, and Welfare.

3. Before any pesticide-chemical residue may remain in or on a raw agricultural commodity, scientific data must be presented to show that the pesticide-chemical residue is safe from the standpoint of the food consumer. The burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-chemical residue.

4. Specific time limits for informal administrative action in establishing tolerances are prescribed to avoid the adverse consequences of inaction and protracted delay. Promptness is vital in this area of regulation to all concerned.

5. Provision is made for the appointment of independent committees of scientific experts selected by the National Academy of Sciences to study proposed regulations establishing tolerances for pesticide chemicals and to make recommendations thereon to the Department of Health, Education, and Welfare.

6. The procedure prescribed for establishing tolerances emphasizes informal proceedings rather than the formal public hearing type of proceedings. This is accomplished in two ways: First, the bill sets up a procedure whereby the manufacturer or formulator most directly concerned with the establishment of a tolerance for a particular pesticide chemical has the right to initiate the proceedings for a tolerance on that chemical by filing a petition. Second, the bill provides for the initial setting of tolerances without a formal public hearing, limiting such hearings to issues which may remain in dispute at the conclusion of the informal proceedings. Existing law requires a formal public hearing before any tolerance can be established and such a proceeding can be initiated only upon the request of a substantial segment of the industry or upon the initiative of the Government.

7. Where the informal procedures do not produce a satisfactory tolerance or exemption the rights of all concerned to a full and fair hearing on the disputed issues are preserved.

8. Enforcement of the adulteration provisions relating to raw agricultural commodities bearing pesticide chemicals is simplified and made more effective, since, under the bill, authority to establish tolerances extends to pesticide chemicals not generally recognized among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, as well as pesticide chemicals which are known to be poisonous or deleterious.

9. Provision is made for the exemption of pesticide chemicals from the requirements of a tolerance in cases where tolerances are not necessary to protect the public health and for the establishment of temporary tolerances for those pesticide chemicals which are used in or on raw agricultural commodities under experimental permits issued by the Department of Agriculture.

Mr. HENDRICKSON. Mr. President, I thank the distinguished Senator from Connecticut for his able and enlightening explanation. I think he has made a fine record for the bill.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Labor and Public Welfare with an [p. 9726] amendment, on page 18, after line 19, to insert:

(o) The Secretary of Health, Education, and Welfare shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) The acceptance of filing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d) (5); or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (l) (2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection.

The amendment was agreed to.

The amendment was ordered to be engrossed and the bill to be read a third time.

The bill was read the third time and passed.

[p. 9727]

1.10b (3) (c) July 8: House concurs in Senate amendment, p. 10095

[No Relevant Discussion on Pertinent Section]

1.10c FOOD ADDITIVES AMENDMENT OF 1958

September 6, 1958, P.L. 85–929, §3(a), (b), 72 Stat. 1784

SEC. 3. (a) Clause (2) of section 402 (a), as amended, of such Act is amended to read as follows: "(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;".

[p. 1784]

(b) Section 402 (a), as amended, of such Act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: "or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409."

[p. 1785]

1.10c (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 2284, 85th Cong., 2d Sess. (1958)

FOOD ADDITIVES AMENDMENT OF 1958

JULY 28, 1958.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. WILLIAMS of Mississippi, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 13254]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, having considered the same, report favorably thereon with an amendment and recommend that the bill, as amended, do pass.

The amendment is as follows:

The amendment strikes all of the text of the introduced bill and inserts in lieu thereof a substitute which appears in the reported bill in italic type.

PURPOSE OF LEGISLATION

The purpose of the legislation is twofold:

(1) To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels.

Existing law bars the use, even at safe levels, of additives which are poisonous or deleterious unless their use is required in production or cannot be avoided by good manufacturing practice. The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food. On the other hand, present law

[p. 1]

entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies.

The Food and Drug Administration has pointed out the dangers to the public health resulting from the failure of the present law to require pretesting of food additives. On the other hand that agency agrees that the present law should be changed to permit the use of additives at safe levels in order to advance our food technology.

While the responsible elements of the affected industries traditionally have voluntarily undertaken to pretest food additives they are willing to assume this responsibility under a statutory mandate. Thus, those elements of the industry which in the past have used harmful additives or additives of unknown toxicity without pretesting will in the future under this legislation be required to assume the same duties as the responsible elements have heretofore voluntarily assumed.

Although there has been complete agreement as to the need for this legislation, there have been differences between the Food and Drug Administration and the affected industries with respect to procedures to be followed in determining the safety of an additive and the method of judicial review of such a determination. With respect to these controversial procedural questions, the committee feels the proposed legislation steers a course which satisfies both the need for protecting the public health and the legitimate interests of industry and Government in fair procedures.

HISTORY OF LEGISLATION

During the 81st Congress, a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics (better known as the Delaney committee, named after its chairman, Congressman James J. Delaney) was created in the House of Representatives to study the need to amend the present Federal Food, Drug, and Cosmetic Act in this respect. After extended hearings, the committee on June 30, 1952, filed a report (H. Rept. No. 2356, 82d Cong., 2d sess.) urging amending the present law so that chemicals employed in or on foods would be subjected to substantially the same safety requirements as exist in the law for new drugs.

Bills to accomplish the objectives of the report were introduced by Congressman Delaney and referred to this committee during the 83d Congress and subsequent Congresses, and other Members of Congress introduced numerous bills differing from the prototype bills primarily with respect to agency procedure and judicial review.

During the 83d Congress, the committee held hearings and reported favorably related legislation providing for the pretesting of, and the establishment of safe tolerances for, pesticide chemicals. This bill was enacted into law (Public Law 518, 83d Cong.).

During the 2d session of the 84th Congress, the Subcommittee on Health and Science, under the chairmanship of the late full committee chairman, J. Percy Priest, held 5 days of hearings on 10 bills dealing with chemical additives in and on food. The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the agency and judicial review procedures to be followed in determining the safety of chemical additives. This disagreement was not resolved, and no chemical additive legislation was enacted during the 84th Congress.

[p. 2]

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) *(A)* if it bears or contains any added poisonous or added deleterious substance, [except] (*except* a pesticide chemical in or on a raw agricultural [commodity,] *commodity and except food additive*) which is unsafe within the meaning of section 406, or *(B)* if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section [408 (a)] *408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing by cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of section 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;* or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; *or (7) if it has been intentionally subjected to ionizing radiation, unless the use of the ionizing radiation was in conformity with a regulation or exemption in effect pursuant to section 409.*

(b) (1) If any valuable constitutent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

[p. 12]

1.10c (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 2422, 85th Cong., 2d Sess. (1958)

FOOD ADDITIVES AMENDMENT OF 1958

AUGUST 18 (legislative day, AUGUST 16), 1958.—Ordered to be printed

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Mr. HILL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H. R. 13254]

The Committee on Labor and Public Welfare, to whom was referred the bill (H. R. 13254) to protect the public welfare by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, having considered the same, report favorably thereon, with amendments, and recommend that the bill do pass.

EXPLANATION

The two amendments which this committee has added to the bill as passed by the House, which are discussed in detail below, do not in any way change the substance or content of the bill which passed the House of Representatives without dissent. They deal, not with the content of that bill, but with related problems regarding the ability of the Department of Health, Education, and Welfare to secure and retain the services of individuals unquestionably qualified to protect and to better the health of our people.

In explanation of the bill sent us by the House, passage of which your committee recommends with additions but without change in any of its provisions, we would point out first that under existing law the Federal Government is unable to prevent the use in foods of a poisonous or deleterious substance until it first proves that the additive is poisonous or deleterious. To establish this proof through experimentation with generations of mice or other animals may require 2 years or even more on the part of the relatively few scientists the Food and Drug Administration is able to assign to a particular problem. Yet, until that proof is forthcoming, an unscrupulous processor of foodstuffs is perfectly free to purvey to millions of our people foodstuffs containing additives which may or may not be capable of producing illness, debility, or death.

[p. 1]

PRINCIPAL PROVISIONS OF LEGISLATION

Substances covered by legislation

Pretesting is required under this legislation only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures (includ-
[p. 4]
ing a review of the existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as "intentional additives."

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term "food additive" as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

CHAPTER IV—FOOD [p. 5]

* * * * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) *(A)* if it bears or contains any added poisonous or added deleterious substance, [except] (*except* a pesticide chemical in or on a raw agricultural [commodity,] *commodity and except a food additive*) which is unsafe within the meaning of section 406, or *(B)* if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section [408 (a)] *408 (a), or (C) if it is, or it bears or con-*

tains, any food additive which is unsafe within the meaning of section 409: Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agicultural commodity; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; *or (7) if it has been intentionally subjected to radia-* [p. 14] *tion, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.*

* * * * * * * [p. 15]

1.10c (3) CONGRESSIONAL RECORD, VOL. 104 (1958)

1.10c (3) (a) Aug. 13: Amended and passed House, pp. 17412, 17414–17415, 17418, 17422–17424

AMENDING FEDERAL FOOD, DRUG AND COSMETIC ACT—USE OF ADDITIVES IN FOOD

Mr. HARRIS. Mr. Speaker, I move to suspend the rules and pass the bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, as amended.

The Clerk read as follows:

Be it enacted, etc., That this act may be cited as the "Food Additives Amendment of 1958."

* * * * *

SEC. 3 (a) Clause (2) of section 402 (a), as amended, or such act is amended to read as follows: "(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409; *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a toler-

> ance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;".
>
> (b) Section 402 (a), as amended, of such act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: "or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409."

[p. 17412]

Mr. HARRIS.

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The purpose of the legislation is two-fold:

First, to protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and second, to advance food technology by permitting the use of food additives at safe levels.

Existing law bars the use, even at safe levels, of additives which are poisonous or deleterious unless their use is required in production or cannot be avoided by good manufacturing practice. The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food. On the other hand, present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies.

The Food and Drug Administration has pointed out the dangers to the public health resulting from the failure of the present law to require pretesting of food additives. On the other hand that agency agrees that the present law should be changed to permit the use of additives at safe levels in order to advance our food technology.

While the responsible elements of the affected industries traditionally have voluntarily undertaken to pretest food additives they are willing to assume this responsibility under a statutory mandate. Thus, those elements of the industry which in the past have used harmful additives or additives of unknown toxicity without pretesting will in the future under this legislation be required to assume the same duties as the responsible elements have heretofore voluntarily assumed.

[p. 17413]

Although there has been complete agreement as to the need for this legislation, there have been differences between the Food and Drug Administration and the affected industries with respect to procedures to be followed in determining the safety of an additive and the method of judicial review of such a determination. With respect to these controversial procedural questions, the committee feels the proposed legislation steers a course which satisfies both the need for protecting the public health and the legitimate interests of industry and Government in fair procedures.

During the 81st Congress, a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics—better known as the Delaney committee, named after its chairman, Congressman JAMES J. DELANEY — was created in the House of Representatives to study the need to amend the present Federal Food, Drug, and Cosmetic Act in this respect. After extended hearings, the committee on June

30, 1952, filed a report—House Report No. 2356, 82nd Congress, 2d session—urging amending the present law so that chemicals employed in or on foods would be subjected to substantially the same safety requirements as exist in the law for new drugs.

Bills to accomplish the objectives of the report were introduced by Congressman DELANEY and referred to this committee during the 83d Congress and subsequent Congresses, and other Members of Congress introduced numerous bills differing from the prototype bills primarily with respect to agency procedure and judicial review.

During the 83d Congress, the committee held hearings and reported favorably related legislation providing for the pretesting of, and the establishment of safe tolerances for, pesticide chemicals. This bill was enacted into law (Public Law 518, 83d Cong.).

During the 2d session of the 84th Congress, the Subcommittee on Health and Science, under the chairmanship of the late full committee chairman, J. Percy Priest, held 5 days of hearings on 10 bills dealing with chemical additives in and on food. The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the agency and judicial review procedures to be followed in determining the safety of chemical additives. This disagreement was not resolved, and no chemical additive legislation was enacted during the 84th Congress.

During the 85th Congress, the Subcommittee on Health and Science held 11 days of hearings on 9 bills. The hearings included 2 days of testimony by a panel of outstanding scientists and experts selected by the National Academy of Sciences at the request of the subcommittee, to give the subcommittee the scientific background with regard to the testing and evaluating of the safety of chemical additives. The subcommittee also heard witnesses from industry, labor, and consumer organizations, representatives from the Department of Health, Education, and Welfare, including those from the Food and Drug Administration, and the chief judge of the third judicial circuit appearing on behalf of the Judicial Conference of the United States.

As a result of the hearings and after consideration of the various bills, the chairman of the subcommittee, Congressman JOHN BELL WILLIAMS, of Mississippi, introduced a clean bill—H. R. 13254 — which was reported unanimously by the subcommittee to the full committee.

The full committee unanimously reported the bill with one amendment which strikes out all after the enacting clause and inserts in place of the introduced bill a substitute. The principal difference between the proposed committee amendment and the introduced bill is the elimination of the provisions in the introduced bill relating to scientific advisory committees. The remaining differences are the result of clerical, technical, and clarifying changes.

Subsequently to the reporting of the bill, as amended in the full committee, the committee adopted unanimously a further amendment to the amendment. This amendment was suggested by Mr. DELANEY who over the years since he was the chairman of a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, has expressed his deep and abiding interest in this subject. While the committee felt that the bill as reported by the committee includes the matter covered by the Delaney amendment in the general language contained in the bill, there was no objection to the addition of the amendment suggested by Mr. DELANEY. This amendment would be inserted on page 24, line 16 of the bill H. R. 13254, as reported; before the semicolon:

> *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found,

after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.

The bill, as amended, has the approval of the Department of Health, Education, and Welfare, and of the organizations which represent the various industry groups which are affected by this legislation. The letter of the Department of Health, Education, and Welfare, endorsing the bill, as amended, reads as follows:

Department of Health,
Education and Welfare,
Washington, August 8, 1958

HON. OREN HARRIS,
Chairman, Committee on Interstate
and Foreign Commerce, House of
Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in reply to your letter of August 5, 1958, acknowledging our endorsement of H. R. 13254, the proposed Food Additives Amendment of 1958, which was reported favorably by our committee with an amendment (in the nature of a substitute) on July 28, 1958, and requesting an expression of our additional views on the bill in view of the amendments recommended by your committee.

The bill would require adequate testing of the safety of so-called intentional or incidental food additives, prior to their marketing and use, so as to establish their safety under the conditions of use to be specified by regulation. Present law, though restrictive as to use of known toxic substances in food, puts the burden on the Government to prove that the substance is a poisonous or deleterious substance. It may take two years or more of laboratory tests on animals to establish this, thus leaving the public without adequate protection in the meantime.

The bill covers those additives not generally recognized by competent experts as having been adequately shown to be safe under the conditions of their intended use. It covers substances that are added intentionally in foods as well as those that may reasonably be expected to become a component of food incidentally or to affect its characteristics. Irradiation of food would be covered by the amendment and would need to be established as safe before commercial use.

Substances commonly used in food before January 1, 1958, and generally recognized as safe because of experience based on such use, would be exempt from the law. Thus, sugar, salt, butter, lard, pepper, and numerous other ingredients would not have to go through the clearance procedures of the bill.

Substances that get into food wholly accidentally, such as paints, used in food processing plants, are not covered by the legislation. These accidental additives, if properly used, cannot reasonably be expected to become a part of food. If an accidental additive which is a poisonous or deleterious substance gets into food, the food would be deemed adulterated and dealt with under the basic 1938 law. The basic law allows no tolerance for such additives.

Other additives not covered by the new amendment are pesticide chemicals on raw agricultural commodities which are already taken care of under the Pesticide Chemicals Amendment (Public Law 518, 83d Cong.); residues of pesticide chemicals in processed foods which result from the proper use of raw materials that have legal pesticide residues; and substances that have already been approved for use in food, under the Food, Drug, and Cosmetic Act, or in the case of meats, under the Meat Inspection Act.

Briefly, the new law would work as follows with respect to additives within its scope:

1. A person who wants to promote a new food additive would have to test it for safety on animals and submit the results of the safety tests to the Food and Drug Administration of the Department of Health, Education, and Welfare.

2. Scientists of the Food and Drug Administration would study the safety data and reach an independent decision as to the safety of the new ingredient for use in our food supply. If the data clearly demonstrate that the material could be safely used, under certain conditions of use, then this Department will, by order, issue a regulation stating safe permissible uses for the material. But if the safety of the additive is not reasonably certain, e.g., if the additive, in appropriate laboratory tests, indicates a potential of inducing cancer, the Department would not permit it and the public health would be safeguarded in a way that has not been possible heretofore.

3. The Department would not be permitted to sanction a use of an additive that promotes deception of consumers in violation of other provisions of the act or that otherwise would result in misbranding or adulteration of food within the meaning of the act. If the quantity of the additive to be used must be limited to safeguard health, then the Department could not allow any quantity in excess of the amount needed to accomplish the intended purpose, even if a greater amount would still be safe. Even the lower amount, of course, could not be allowed unless it is safe.

4. A person adversely effected by the Secretary's order would be entitled to a full administrative hearing on his objections. In case of actual controversy as to the Secretary's action after hearing, there would be a further oppor-

[p. 17414]

tunity for judicial review of the validity of the order on the basis of the record.

The Secretary's action after hearing would have to be based upon a fair evaluation of the entire record at the hearing. On judicial review, the United States Court of Appeals would be required to sustain the findings of the Secretary if based upon a "fair evaluation of the entire record at the hearing"; it would have to reverse the order of the Secretary if it is not "based upon a fair evaluation of the entire record" or if it fails to include a statement setting forth in detail the findings and conclusions upon which the order is based. The "fair evaluation" provision is quite acceptable to the Department, because it is the standard to which we are accustomed to adhere.

5. The amendment would become effective in three stages:

(a) The Department would be authorized to start making determinations as to the safety of a food additive when the law is enacted.

(b) The provisions of section 3 of the legislation (which will have the effect of permitting seizure, injunction suits, and criminal prosecutions on account of the shipment by interstate commerce of an additive or food containing an additive, which has not been determined to be safe) would take effect 180 days after the enactment of the legislation. This is required because it will take a certain amount of time to make the necessary determinations of safety.

(c) With respect to any particular commercial use of a food additive which began before January 1, 1958, industry would be allowed 12 months after the effective date of section 3 (18 months after date of enactment) to present the necessary data to secure a regulation prescribing the conditions under which the additive may be safely used. This would permit an orderly transition from present procedures to those of the amendment. Where there would be no undue hazard to the public health and conditions necessitate further extension, the Secretary would have the authority to grant up to an additional 12 months for this clearance of old additive uses.

This is what is commonly referred to as the "grandfather clause" of the legislation but it is not a grandfather clause as that term is generally used. The grandfather clause, as proposed in some of the bills before your committee would have exempted substances used in food prior to enactment of the legislation from having to meet its requirements at all. This Department opposed such a provision because prior use in food would not be an adequate substitute for a showing of safety.

In lieu of such a grandfather clause, the present legislation, as indicated above, prescribes a reasonable transition period which will guarantee prompt decision on the status of additives already in use in food and will grant industry a reasonable period of time in which to compile the data it has on the safety of the additives and if necessary to perform additional tests.

If the proposed legislation is not enacted, substances of unknown toxicity, which would be granted a limited time in which to meet the safety provisions of H. R. 13254, may continue to be used indefinitely and additional additives may be marketed for use in food without any requirement that their safety first be established. So a reasonable choice is not between allowing the old additives or not allowing them. The choice is between establishing their safety as soon as is practical under the transition period allowed in H. R. 13254 or allowing their continued use without any requirement that their safety be reevaluated. However, the transitional period does not protect additives whose toxicity is known and which are barred under present law. Food containing such additives could meanwhile be proceeded against under present law.

We would like, also, to make special mention of: (1) The advisory committee procedure; (2) the cancer question; and (3) the functional value question.

1. The advisory committee procedure was incorporated in the proposed legislation which this Department submitted to Congress (H. R. 6747) to give industry an opportunity to have petitions reviewed by a panel of outside scientists. We do not object to the committee's deletion of the procedure, because the Department already has the privilege of making inquiry of competent outside scientists on technical matters.

2. The widespread interest in cancer led to suggestions that the food additives legislation should mention the disease by name and forbid the approval of any substance that is found upon test to cause cancer in test animals. This Department is in complete accord with the intent of these suggestions—that no substance should be sanctioned for uses in food that might produce cancer in man. H. R. 13254, as approved by your committee, will accomplish this intent, since it specifically instructs the Secretary not to issue a regulation permitting use of an additive in food if a fair evaluation of the data before the Secretary fails to establish that the proposed use of the additive will be safe. The scientific tests that are adequate to establish the safety of an additive will give information about the tendency of an additive to produce cancer when it is present in food. Any indication that the additive may thus be carcinogenic would, under the terms of the bill, restrain the Secretary from approving the proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer and thus would be safe under the proposed conditions of use. This would afford good, strong public health protection.

There are many serious conditions other than cancer that may be caused or aggravated by the improper use of chemicals. It is manifestly impracticable to itemize all of them in a bill. To single out one class of diseases for special mention would be anomalous and could be misinterpreted. Hence, in drafting the Department's bill (H. R. 6747) we chose general language that would restrain any use of an additive that would have any adverse effect on the public health. This approach has been followed in H. R. 13254.

At the same time, if it would serve to allay any lingering apprehension on the part of those who desire an explicit statutory mandate on this point, the Department would interpose no objection to appropriate mention of cancer in food additives legislation. If the specific disease were referred to in the law, it would, however, be important for everyone to have a clear understanding that this would in no way restrict the Department's freedom in guarding against other harmful effects from food additives.

It would be important, also, to use language that would provide the intended safeguards without creating unintended and unnecessary complications. For example, the language suggested by some to bar carcinogenic additives would, if read literally, forbid the approval for use in food of any substance that causes any type of cancer in any test animal by any route of administration. This could lead to undesirable results which obviously were not intended by those who suggested the language. Concentrated sugar solution, lard, certain edible vegetable oils, and even cold water have been reported to cause a type of cancer at the site of injection when injected repeatedly by hypodermic needle into the same spot in a test animal. But scientists have not suggested that these same substances cause cancer when swallowed by mouth.

The enactment of a law which would seem to bar such common materials from the diet on the basis of the evidence described above, would place the agency that administered it in an untenable position. The agency would either have to try to enforce the law literally so as to keep these items out of the diet—evidently an impossible task—or it would have to read between the lines of the law an intent which would make the law workable, without a clear guide from Congress as to what was meant.

This difficulty could readily be avoided, if there is still a desire to make specific mention of cancer in the bill, by providing that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate to the evaluation of the safety of food additives, to induce cancer in animals." Such language could be appropriately inserted as a proviso before the semicolon on page 24, line 16, of the bill as reported by your committee.

3. The functional value provision of this Department's bill (H. R. 6747) was proposed to prevent the useless addition of toxic chemicals to food, to prevent the use of more of an additive which requires limitation in the interest of safety than is needed to accomplish the intended benefit, and to prevent deception of the consumer. Some objected to this provision as it appeared in H. R. 6747, in the belief that it would require this Department, in some respects, to make subjective judgments on questions not readily resolved on a factual basis. H. R. 13254 is, clearly, not open to this objection but it retains the essential consumer protection features that were to be accomplished by the functional value provision in the following manner:

(a) If the additive requires a tolerance limitation to insure its safe use:

(1) The Secretary may permit the proposed use only if the data before him show that it would accomplish the intended physical or other technical effect. This would prevent the useless additional toxic chemicals to food.

(2) The Secretary would only fix the tolerance limitation at the level reasonably required to accomplish the physical or other technical effect (provided, of course, this level is safe). This would prevent the use of more of a toxic chemical than is needed to accomplish the intended effect.

(b) The Secretary would be forbidden to permit use of an additive if the data before him showed that the proposed use would promote deception of the consumer in violation of, or would otherwise result in adulteration or misbranding within the meaning of the Federal Food, Drug, and Cosmetic Act.

In conclusion, we strongly urge the enactment of the bill by the present Congress in order to close a serious gap in the present law.

In view of the urgency of this report, time has not permitted its submission to the Bureau of the Budget for advice in accordance with the usual procedure.

Sincerely yours,

Elliot L. Richardson
Assistant Secretary

Great credit is due the chairman and the members of the Subcommittee on Health and Science who worked so conscientiously to bring about substantially unanimous agreement with regard to this legislation which has been in the making for 6 years.

Instead of attempting to explain the bill, as amended, section by section, I feel that it would be easier to present an analysis of the principal provisions of this legislation.

[p. 17415]

Mr. POFF. Mr. Speaker, I am in favor of the bill.

Mr. Speaker, I applaud and commend the chairman and members of the Committee on Interstate and Foreign Commerce for their work and the results of their work on H. R. 13254 to amend the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety for human consumption.

As I understand the bill, pretesting of additives is required only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures or, in the case of substances in use prior to January 1, 1958, by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as intentional additives.

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as incidental additives.

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packaging, transporting, or holding food.

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[p. 17418]

Mr. McDONOUGH. Mr. Speaker, I was a member of the Delaney committee which held numerous hearings on this subject in various parts of the United States. Although this legislation is necessary in order to protect the public, in my opinion, it is not as positive nor as strong as it should be on the basis of our hearings and the information that we obtained from witnesses. It is necessary largely because of the increase in the number of vendors and the competition between the various vendors of foods with added chemical additives to make the foods look better but which sometimes reduces the protein value and the nutritive value of the food. It is unfortunate that we have to have such legislation as this, but we have found it is necessary. Great volumes of food are turned out. All kinds of food is produced in ways to make it more attractive and to make it easier to bake cakes and to make it easier to bake pies and to make it easier to keep bread from molding on the shelves and so on, but with very little thought in many instances given to the effect these chemicals have on the nutritive value of the food. I favor this legislation as one means of protecting the public because I think that many of these chemicals are very dangerous in many instances and may be harmful to the health of many people throughout the Nation. These additives should be pretested before they are used. I trust, however, that the Committee on Interstate and Foreign Commerce will give further study and consideration to chemical additives to food and propose additional legislation to control the use of dangerous and deleterious chemicals which could and may be the source of infectious and contagious disease. The public health must be protected. Some of the cases that the Delaney committee heard testimony about from competent witnesses created doubt as to whether the use of these chemical additives in food did or did not create favorable conditions for the development of cancerous growth and other noxious diseases.

The following parts of the committee report on H. R. 13254 will give its purpose, history, and powerful provisions:

PURPOSES OF LEGISLATION

The purpose of the legislation is twofold:

1. To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and

2. To advance food technology by permitting the use of food additives at safe levels.

Existing law bars the use, even at safe levels, of additives which are poisonous or deleterious unless their use is required in production or cannot be avoided by good manufacturing practice. The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food. On the other hand, present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies.

The Food and Drug Administration has pointed out the dangers to the public health resulting from the failure of the present law to require pretesting of food additives. On the other hand that agency agrees that the present law should be changed to permit the use of additives at safe levels in order to advance our food technology.

While the responsible elements of the affected industries traditionally have voluntarily undertaken to pretest food additives they are willing to assume this responsibility under a statutory mandate. Thus, those elements of the industry which in the past have used harmful additives or additives of unknown toxicity without pretesting will in the future under this legislation be required to assume the same duties as the responsible elements have heretofor voluntarily assumed.

Although there has been complete agreement as to the need for this legislation, there have been differences between the Food and Drug Administration and the affected industries with respect to procedures to be followed in determining the safety of an additive and the method of judicial review of such a determination. With respect to these controversial procedural questions, the committee feels the proposed legislation steers a course which satisfies both the need for protecting the public health and the legitimate interests of industry and Government in fair procedures.

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[p. 17422]

PRINCIPAL PROVISIONS OF LEGISLATION

Substances covered by legislation

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The legislation covers substances which are added intentionally to food. These additives are generally referred to as intentional additives.

The legislation also covers substances which my reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as incidental additives.

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food-processing plants, are not covered by the legislation. These additives are generally referred to as accidental additives, since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term food additive as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

[p. 17423]

Mr. HARRIS.

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NEXT OBJECTIVE: SAFETY OF COSMETICS

Mr. Speaker, I am pleased that we are finally passing a bill on chemical additives in food after all of these years of effort. I wish it were a better bill. But it can accomplish a great deal of good if it is enacted into law. I congratulate all of those Members who have had a part in shaping the bill, and I sincerely hope the Senate will have an opportunity to act on the legislation so that a bill can be sent to the White House.

I now serve notice, Mr. Speaker, that I intend to do everything I can beginning at the start of the next session of Congress to enact similar legislation dealing with the safety of materials and chemicals used in cosmetics. I hope it does not take as long on that as it has taken to get action on the food additives. The problem is much the same and the solution also is much the same—that is, legislation to require the manufacturers to prove the safety of the chemicals they use rather than to force the Government to prove the chemicals to be unsafe.

The SPEAKER. The question is: Will the House suspend the rules and pass the bill, as amended?

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table. [p. 17424]

1.10c (3) (b) Aug. 23: Amended and passed Senate, pp. 19358–19359

PROHIBITION OF USE OF UNTESTED ADDITIVES IN FOOD

The PRESIDING OFFICER. Calendar No. 2487, House bill 13254, was passed to the foot of the calendar. The bill will be stated by title for the information of the Senate.

The Legislative Clerk. A bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

Mr. HILL. Mr. President, I ask unanimous consent to have printed in the Record at this point a statement which I have prepared on the bill.

There being no objection, the statement was ordered to be printed in the Record, as follows:

This bill, which is the result of some 6 years of very intensive hearings held by the House Committee on Interstate and Foreign Commerce, was reported unanimously by that committee to the House, passed the House without dissent and has been unanimously reported by the Committee on Labor and Public Welfare.

The bill has as its objective the correction of two deficiencies in the existing laws under which we undertake to assure the safety of the foods sold to the people of the United States.

In the first place, this legislation would require the processor of foodstuffs who proposes to add to the food any new chemical additive to first prove that the proposed addition will be safe. Under present law the burden of proving any particular additive poisonous or deleterious to humans lies with the Food and Drug Administration. Sometimes a chemical may be added to foodstuffs and used for a considerable period of time before anyone begins to suspect that it may be having ill effects. When and if suspicion has been aroused, more time passes before the Food and Drug Administration can schedule it for investigation. The scientists of our Food and Drug Administration then undertake investigatory procedures involving testing the chemical additives on small animals. This may take 2 years or even longer. In the meantime, millions of people may be eating the foodstuffs containing the perhaps seriously deleterious additive. An overwhelming percentage of America's food processors of course have [p. 19358] voluntarily undertaken to thoroughly test any additives before using them. This bill would require that all processors do so and that no new additives be used without their safety having first been established. The burden of proof is placed where it belongs: Not on the Government, but on the concern which intends to add the chemical to our food.

The second change in existing law would permit American industry to promote new technological developments in food handling calculated to make foods more tasteful and appetizing, to enable them to be kept longer, or to otherwise improve them, through the use of additives now proscribed under a blanket provision of existing law. This legislation, which has the approval of the Food and Drug Administration, would permit the use of additives at safe levels in order to advance our food technology.

I have said that the bill before us passed the House unanimously. I have also pointed out that it has the support of the Food and Drug Administration, which is charged by law with responsibility for protecting the public's health with respect to the foods it eats. I am happy, Mr. President, to be able to also announce that our records indicate that this measure now has the overwhelming support of the major industrial and business concerns which would be affected by it. Its prompt passage is urged not only by the Administration and the committee but by such business groups as:

"National Canners Association; National Dairy Products Corp.; Kraft Foods Division; Grocery Manufacturers of America; Millers National Federation; American Bakers Association; Manufacturing Chemists Association; and the Dairy Industry Committee, speaking for: the American Butter Institute; the American Dairy Milk Institute; the Evaporated Milk Association; the International Association of Ice Cream Manufacturers; the Milk Industry Foundation; the National Cheese Institute; and the National Creameries Association.

The bill will further strengthen the administration of the Pure Food and Drug Act and the protection afforded the American people by that act.

Mr. President, I note the presence of the distinguished senior Senator from Montana, Mr. MURRAY. He is a former chairman of the Senate Committee on Labor and Public Welfare and is always greatly interested in the strengthening of the Pure Food and Drug Act. We owe much to him and his able and devoted leadership.

Questions were raised concerning the interpretation of two words in the bill. The questions were taken up with the Department of Health, Education, and Welfare. Following is a letter from the Department giving its interpretation of those words:

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE,
Washington, August 20, 1958

Hon. LISTER HILL,
Chairman, Committee on Labor, and
Public Welfare, United States Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: Two questions have arisen about the correct interpretation and the legislative intent of section 2 of H. R. 13254, referred to as the "Food Additives Amendment of 1958." Those questions, and the viewpoints of this Department and of the Food and Drug Administration, are as follows:

1. Does the word "substance," as used in that section, include a food or food component consisting of two or more ingredients? Our interpretation is in the affirmative.

2. Do the words "common use," as used in that section, include a wide use of such a substance by many consumers, even though such a substance may have been used by only a single manufacturer of food or food components? Again our answer is in the affirmative.

We would greatly appreciate it if you would place this letter in the CONGRESSIONAL RECORD in connection with the presentation of the bill for Senate consideration.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary

I would add that the term "otherwise affecting the characteristics of any food" refers to an effect not generally recognized as safe among experts qualified by scientific training and experience to evaluate the safety of food additives; but innocuous effects of packaging, such as protection from dirt, retarding moisture loss, preserving shape, providing convenience in use, handling and storage, and the like, would not be covered.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Labor and Public Welfare with amendments, on page 15, after line 5, to insert a new section, as follows:

SEC. 8. The annual rate of basic compensation of the Commissioner of Food and Drugs shall be $20,000.

And after line 7, to insert a new section, as follows:

SEC. 9. Section 208 (g) of the Public Health Service Act, as amended (42 U.S.C. 210 (g)), is amended by striking out the phrase "in the professional and scientific service" and inserting in lieu thereof the phrase "in the professional, scientific, and executive service" and by striking out the phrase "of specially qualified scientific or professional personnel" and inserting in lieu thereof "of specially qualified scientific, professional, and administrative personnel."

Mr. HILL. Mr. President, I ask that the committee amendments be agreed to en bloc.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. WILLIAMS. Mr. President, I offer the amendments which I send to the desk and ask to have stated.

The PRESIDING OFFICER. The amendments offered by the Senator from Delaware will be stated.

The LEGISLATIVE CLERK. On page 2,

line 21, after the word "Act," it is proposed to insert the following: ", the Poultry Products Inspection Act (21 U.S.C. 451 and the following)."

On page 15, line 3, after the words "pursuant to," it is proposed to insert the following: "the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or."

Mr. HILL. Mr. President, let me say to the distinguished Senator from Delaware that these are very fine amendments. The Department of Agriculture favors the amendments. The Department of Health, Education, and Welfare has no objection to them. I hope the amendments may be agreed to.

The PRESIDING OFFICER. The question is on agreeing to the amendments offered by the Senator from Delaware.

The amendments were agreed to.

The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time, and passed.

[p. 19359]

1.10c (3) (c) Aug. 23: House concurs in Senate amendment, p. 19641

[No Relevant Discussion on Pertinent Section]

1.10d COLOR ADDITIVE AMENDMENTS OF 1960

July 12, 1960, P.L. 86–618, Title I, §§102(a) (1), (2), 105(c), 74 Stat. 397, 404

COLORS OR COLORED ARTICLES—WHEN DEEMED TO BE ADULTERATED OR MISBRANDED FOODS, DRUGS, OR COSMETICS

Food

SEC. 102. (a) (1) Clause (2) (A) of section 402 (a), as amended, of such Act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than one which is (i) a pesticide chemical [p. 397] in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive".

(2) Section 402 (c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706 (a)."

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[p. 398]

CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

SEC. 105. Such Act is further amended by— [p. 403]

* * * * * * *

(c) striking out "harmless coloring" in section 402 (d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

[p. 404]

1.10d (1) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 795, 86th Cong., 1st Sess. (1959)

COLOR ADDITIVE AMENDMENTS OF 1959

AUGUST 21, 1959.—Ordered to be printed

Mr. HILL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany S. 2197]

The Committee on Labor and Public Welfare, to whom was referred the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

EXPLANATION

S. 2197 is designed to better protect the public health with respect to procedures necessary to assure the safety of color additives in foods, drugs, and cosmetics and to authorize the use of such color additives as have been predetermined to be perfectly safe in the amounts in which they are to be used. The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act with a scientifically sound and uniform system for the listing of color additives of any kind which may be safely used in food, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

Under existing law coal-tar colors may not be used in foods, drugs, or cosmetics unless they have been certified by the Food and Drug Administration as harmless and suitable for use. A recent Supreme Court decision has defined the "harmless" principle as meaning harmless regardless of the quantity of the coal-tar color which is being used. Thus, a color must be certified if any

[p. 1]

quantity or concentration of the color is harmful, even though in lesser concentrations it may be perfectly safe. Because of this principle, as defined by the Supreme Court, it has been necessary for the Food and Drug Administration to withdraw certification of seven food colors. Seventeen additional colors have been proposed for delisting. The effect of the application of the "harmless" principle in terms of existing law is to cause many of the coal-tar colors widely used in industry to be no longer available, and the number of colors withdrawn will eventually seriously handicap manufacturers of foods, drugs, and cosmetics in the production of products in the manner that is customary and usual.

Many food industries find themselves seriously affected by the delisting of colors. If additional proposed delistings are accomplished, similar effect is faced by drug and cosmetic industries. The very existence of many products depends upon the use of suitable color.

This legislation is necessary, because it will give the Secretary of Health, Education, and Welfare a flexibility, which he does not have under the present law, to certify coal-tar colors within tolerance limits which he determines are safe.

Two amendments to the bill as originally introduced were adopted by the committee. Both amendments were developed cooperatively by the committee staff, representatives of the industries concerned, and representatives of the Food and Drug Administration. Both have been declared acceptable by the Administration and by industry. Their objectives are, first, to permit those additives found "safe" by the Secretary under the procedures set forth in the Food Additives Amendments Act of 1958 to be considered "safe" when used as color additives, and, secondly, to relieve the Administration from the obligation of requiring the use of certain analytical methods, when, in its opinion, they are not needed.

The bill as amended has the endorsement of the Administration and of the following business groups which have concerned themselves with the legislation: The Certified Color Industry Committee, the Toilet Goods Association, the National Association of Margarine Manufacturers, the International Association of Ice Cream Manufacturers, the Grocery Manufacturers of America, and the National Confectioners Association.

S. 2197 was introduced at the request of the Department of Health, Education, and Welfare with the approval of the Bureau of the Budget.

[p. 2]

II. SECTIONAL ANALYSIS

TITLE I—AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETICS ACT

* * * * * * *

Section 102(a)

Paragraph (1) adds color additives to the exceptions from section 402(a) (2) (A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." This paragraph of the bill makes explicit, with regard to color additives, the interpretation of the Supreme Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958), that section 406(a) of existing law—which authorizes the establishment of tolerances for poisonous or deleterious substances added to food where the additive is required in the production of the food or cannot be avoided by good manufacturing practice—cannot serve as a basis for allowing the use of coal-tar colors where marketability of a food depends on such coloring. Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph (2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act as

[p. 13]

enacted by the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the provisos to section 402(c) with respect to the use of color on oranges. (See Public Law 86–2.) (Sec. 406(b) of the act would be repealed under another section of the bill.) The effect of these changes would be to (*a*) make the new provisions applicable to all color additives, whether or not they are coal-tar colors; (*b*) extend them to the color additive itself before being added to food; and (*c*) use the technique of the pesticide chemicals amendment and food additives amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended sec. 706) of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

[p. 14]

Section 105

Contains appropriate changes of cross-references in, and other conforming amendments to, section 301(i) (false use of required marks), 303(c)(3) (guarantee that coal-tar color is certified), and 402(d) (nonnutritive substances in confectionery) of the basic act.

[p. 17]

CHAPTER IV—FOOD

* * * * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance, [except a pesticide chemical in or on [p. 21] a raw agricultural commodity and except food additive)] *(other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive)* which is unsafe within the meaning of section 406, or

* * * * * * *

(B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409[2a].

(b)(1) If any valuable constitutent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

[(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: . . . *Provided* . . . That, without regard to the requirements of section 406(b) and 701(e), the Secretary shall promptly establish, and may from time to time amend, regulations (1) prescribing the conditions (including quantitative tolerance limitations) under which the coal-tar color known as Citrus Red No. 2 (more particularly to be defined in such regulations) may be safely used in coloring the skins of oranges which are not intended or used for processing (or, if so used, are oranges designated in the trade as "packing house elimination"), and which meet minimum maturity standards established by or under the laws of the States in which the oranges are grown, (2) providing for separately listing such color solely for such use on such oranges, and (3) providing for the certification of batches of such color, with or without harmless diluents, for such restricted use; and such oranges, if colored prior to September 1, 1961, and to the enactment by the Congress (subsequent to the date of enactment of this proviso) of general legislation for the listing and certification of food color additives under safe tolerances, in conformity with this proviso and such regulations, with Citrus Red No. 2 from a batch certified in accordance with such regulations, shall not be deemed to be adulterated within the meaning of this paragraph.]

(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

[p. 22]

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except [harmless coloring] *authorized coloring*, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

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[p. 23]

1.10d (2) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 1761, 86th Cong., 2d Sess. (1960)

COLOR ADDITIVE AMENDMENTS OF 1960

JUNE 7, 1960.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. HARRIS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 7624]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments, as they appear in the reported bill, are as follows:

* * * * * * * [p. 1]

PURPOSE OF LEGISLATION

The purpose of this bill is to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerances, under which such additives may be safely used.

GENERAL SUMMARY

The committee bill—

(1) takes "color additives" out of the scope of the Food Additives Amendment of 1958;

(2) repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604);

(3) enacts new, integrated provisions for the separate listing of suitable "color additives," safe for use in food, drugs,

or cosmetics, under such conditions (including tolerance limitations) as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted;

(4) provides for the certification (or exemption from certification) of listed color additives for such permitted uses;

(5) adapts the adulteration and other provisions of the Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above-mentioned changes; and

(6) contains transitional provisions for commercially established colors.

HEARINGS

Extensive hearings were held by the committee on this legislation in January, February, March, and May 1960 and a large number of witnesses were heard. The committee also heard from a distinguished group of scientific experts, selected by the President of the National Academy of Sciences, which discussed the scientific problems involved in this legislation, with special emphasis on the Delaney anticancer clause.

BACKGROUND INFORMATION

Under the Federal Food, Drug, and Cosmetic Act, the treatment of color additives differs radically as between so-called coal-tar colors and other colors.

1. *Coal-tar colors.*—The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived.

So-called coal-tar colors are regulated under the act through similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). The act requires the Secretary of Health, Education, and Welfare to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, and cosmetics.

Food containing a coal-tar color is deemed adulterated under section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406. Section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food and to provide for certifying batches of such colors.

A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504. Section

504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors.

A cosmetic (other than a hair dye, which is defined to exclude eyelash and eyebrow dyes) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604. Section 604 then directs the Secretary to provide for listing of coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

The Secretary of Health, Education, and Welfare is without authority to admit a coal-tar color to listing under tolerance limitations; it must be harmless per se in order for the Secretary to admit it to listing *(Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958)).

One exception to the prohibition against the listing of a coal-tar color under tolerance limitations was made by the Congress in Public Law 86–2 to permit the temporary listing and certification of the color Citrus Red No. 2 for the coloring of mature oranges under tolerances found to be safe by the Secretary of Health, Education, and Welfare.

2. *Other colors.*—A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirements in the case of cosmetics or drugs except as pretesting may be required for a coloring component as an incident to official clearance of a "new drug" under the "new drug" provisions of the act.

Non-coal-tar coloring materials used in food, when such materials are not generally recognized by experts as safe, are classified as "food additives" under the Food Additives Amendment of 1958 (Public Law 85–929). Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed to be adulterated if the additive is unsafe within the meaning of section 409. Under section 409 the food additive is deemed unsafe unless it and its use, or intended use, conform to a regulation issued by the Secretary announcing the conditions, including the establishment of tolerance limitations, under which the additive may be safely used. Food colors which were in commercial use before January 1, 1958, are allowed a grace period not later than March 6, 1961, for compliance with the provisions of the Food Additives Amendment of 1958. Such "food additive" colors, however, are not subject to any requirement of "batch" certification. [p. 7]

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EXPLANATION OF PRINCIPAL COMMITTEE AMENDMENTS

(1) Agricultural chemicals affecting color (p. 3, beginning on line 10 of reported bill)

The committee was advised that certain pesticide chemicals used in fruit production have the effect not only of protecting the trees against plant diseases but also of supporting or otherwise affecting natural plant processes which thus result in the production of better color and finish in the fruit. Also, some plant growth regulators, when applied to plants, likewise enhance the development of normal color in the produce of such plants. Some fear has been expressed that such chemicals and plant regulators could be considered to fall within the scope of the definition of "color additive" in section 101(c) of the bill since they have the ability to promote the coloring of raw agricultural commodities.

The committee agrees with the Secretary of Health, Education, and Welfare that such chemicals and plant nutrients are not color additives within the meaning of the basic definition of color additive in this bill, since they merely promote the development of the natural color of produce as the result of the normal physiological processes of the plant or produce. To make this clear, however, the committee has inserted an amendment to the effect that the term "color additive" in section 101(c) of the bill shall not be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical which affects the color of fruit or other raw agricultural commodity which is the produce of the soil solely through its effect on plant metabolism or enzymatic processes either before or after harvest. Pesticide chemicals are regulated under section 408 of the Federal Food, Drug, and Cosmetic Act and under the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163; 7 U.S.C. 135–135k), and there is no necessity for subjecting them to additional regulation under the color additive amendments when their sole effect on color is through such metabolic or enzymatic processes.[1]

It is not the intention of the committee, however, to exempt from the provisions of this bill any chemical or nutrient if it also contains a dye, pigment, or other substance whose function is to impart color to the fruit or other raw agricultural commodity.

The views of the Secretary of Health, Education, and Welfare in letters to the committee dated February 8, 1960, and April 21, 1960, and the letter of the Assistant Secretary of Agriculture dated April 14, 1960, expressing their views on this subject, in which the committee concurs, are shown in the appendix to this report.

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[1] Under a recent amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (Public Law 86–139) nematocides, plant regulators, defoliants, and dessicants have been classified as pesticide chemicals.

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SECTION-BY-SECTION ANALYSIS OF "COLOR ADDITIVE AMENDMENTS OF 1960"

* * * * * * *

[p. 18]

Section 102(a)

Paragraph (1) adds color additives to the exceptions from section 402(a)(2)(A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph 2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act as enacted by the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the provisos to section 402(c) with respect to the use of color on oranges. (See Public Law 86–2.) (Sec. 406(b) of the act would be repealed under another section of the bill.) The effect of these changes would be to (*a*) make the new provisions applicable to all color additives, whether or not they are coal-tar colors; (*b*) extend them to the color additive itself before being added to food; and (*c*) use the technique of the pesticide chemicals amendment and food additives amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended sec. 706) of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

[p. 23]

Section 105

Contains appropriate changes of cross-references in, and other conforming amendments to sections 301(i) (false use of required marks), 303(c)(3) (guarantee that coal-tar color is certified), and 402(d) (nonnutritive substances in confectionery) of the basic act.

[p. 29]

CHAPTER IV—FOOD

* * * * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance [(except a pesticide chemical in or on a raw agricultural commodity and except a food additive)] *(other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive)* which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

(b) (1) If any valuable constitutent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

[(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act

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and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit: *Provided further*, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as "packing house elimination"), the skins of which have been colored at any time prior to May 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F. D. & C. Red 32, or certified after such enactment as External D. & C. Red 14 in accordance with section 21 Code of Federal Regulations, part 9: *And provided further*, That, without regard to the requirements of sections 406(b) and 701(e), the Secretary shall promptly establish, and may from time to time amend, regulations (1) prescribing the conditions (including quantitative tolerance limitations) under which the coal-tar color known as Citrus Red No. 2 (more particularly to be defined in such regulations) may be safely used in coloring the skins of oranges which are not intended or used for processing (or, if so used, are oranges designated in the trade as "packing house elimination"), and which meet minimum maturity standards established by or under the laws of the States in which the oranges are grown, (2) providing for separately listing such color solely for such use on such oranges, and (3) providing for the certification of batches of such color, with or without harmless diluents, for such restricted use; and such oranges, if colored prior to September 1, 1961, and to the enactment by the Congress (subsequent to the date of enactment of this proviso) of general legislation for the listing and certification of food color additives under safe tolerances in conformity with this proviso and such regulations, with Citrus Red No. 2 from a batch certified in accordance with such regulations, shall not be deemed to be adulterated within the meaning of this paragraph.]

(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except [harmless] *authorized* coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

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B. MAJOR CHANGES PROPOSED

The bill would change existing law in the following respects:

1. *Uniform criteria of admissibility.*—It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics, other than hair dyes. This would be accomplished by excepting color additives, as defined in the bill, from the term "food additive"; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section (sec. 706), comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification (or exemption from certification); and making other amendments to the act to mesh with these provisions.

The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives, but also to synthetic substances so related in their chemical structure to a coal-tar constitutent as to be capable of derivation therefrom even when not actually so derived. The present bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term "coal-tar color." The bill would, therefore, establish common ground rules for all such colors.

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Section 102(a)

Paragraph (1) adds color additives to the exceptions from section 402(a) (2) (A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." This paragraph of the bill makes explicit, with regard to color additives, the interpretation of the Supreme Court in *Flemming* v. *Florida Citrus Exchange* (358 U.S. 153 (1958)), that section 406(a) of existing law—which authorizes the establishment of tolerances for poisonous or deleterious substances added to food where the additive is required in the production of the food or cannot be avoided by good manufacturing practice—cannot serve as a basis for allowing the use of coal-tar colors where marketability of a food depends on such coloring. Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph (2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act as enacted by the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the provisos to section 402(c) with respect to the use of color on oranges (see Public Law 86–2). (Sec. 406(b) of the act would be repealed under another section of the bill). The effect of these changes would be to (*a*) make the new provisions applicable to all color additives, whether or not they are coal-tar colors; (*b*) extend them to the color additive itself before being added to food; and (*c*) use the technique of the Pesticide Chemicals Amendment and Food Additives Amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended sec. 706) of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

Paragraph (3) adds to section 403 of the basic act a new subsection (l), whereby a food which is a color additive is deemed [p. 69] misbranded unless packaged and labeled in accordance with packaging and labeling requirements, if any, contained in regulations issued under section 706 (as amended by the bill). (Under the basic act's definition of "food," a color additive intended to be added to food is itself considered "food" before it is so added.)

Section 102(b)

Paragraph (1) amends section 501(a)(4) of the basic act to deem adulterated any drug containing a color additive solely for purposes of coloring, and any color additive which (with respect to its use in or on drugs) is intended solely for coloring purposes, if these are unsafe within the meaning of section 706(a) of the act. This would replace the present provision of section 501(a)(4), which deems a drug adulterated if it bears or contains for purposes of coloring only, a coal-tar color other than one from a batch that has been certified under section 504. (Sec. 504 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 502 of the basic act a new subsection (m) deeming misbranded a drug which is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with packaging and labeling requirements, if any, contained in regulations issued under section 706. (A color additive is, under the definition of "drug" in the basic act, itself a drug when intended for use as a component of drugs.)

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1.10d (3) CONGRESSIONAL RECORD

1.10d (3) (a) VOL. 105 (1959), Aug. 24: Amended and passed Senate, p. 16780

1.10d (3) (b) VOL. 106 (1960), June 25: Discharged, amended, and passed House, pp. 14356–14358, 14373, 14377

Mr. HARRIS.

* * * * *

COLOR ADDITIVES AMENDMENTS

(H.R. 7624)

Mr. Speaker, the committee bill, H.R. 7624, was reported unanimously by the Committee on Interstate and Foreign Commerce. It is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act, with a specifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

GENERAL SUMMARY

In brief, the committee bill, first, takes color additives out of the scope of the food additives amendment of 1958; second, repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); third, enacts new, integrated provisions for the separate listing of suitable color additives, safe for use in food, drugs or cosmetics, under such conditions — including tolerance limitations — as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted; fourth, provides for the certification (or exemption from certification) of listed color additives for such permitted uses; fifth, adapts the adulteration and other provisions of the Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above-mentioned changes; and sixth, contains transitional provisions for commercially established colors.

[p. 14356]

1. COAL-TAR COLORS

The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived.

So-called coal-tar colors are regulated under the act through similar sets of provisions in chapters IV Food, V Drugs, and VI Cosmetics. The act requires the Secretary of Health, Education, and Welfare to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, and cosmetics.

Food containing coal-tar color is deemed adulterated under section 402 (c) of the act unless the color is from a batch certified by the Secretary under section 406. Section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food and to provide for certifying batches of such colors.

A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504. Section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors.

A cosmetic—other than a hair dye, which is defined to exclude eyelash and eyebrow dyes—containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604. Section 604 then directs the Secretary to provide for listing of coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

The Secretary of Health, Education, and Welfare is without authority to admit a coal-tar color to listing under tolerance limitations; it must be harmless per se in order for the Secretary to admit it to listing—*Flemming* v. *Florida Citrus Exchange* (358 U.S. 153 (1958).

One exception to the prohibition against the listing of a coal-tar color under tolerance limitations was made by the Congress in Public Law 86-2 to permit the temporary listing and certification of the color citrus red No. 2 for the coloring of mature oranges under tolerances found to be safe by the Secretary of Health, Education, and Welfare.

2. OTHER COLORS

A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirements in the case of cosmetics or drugs except as pretesting may be required for a coloring component as an incident to official clearance of a "new drug" under the "new drug" provisions of the act.

Non-coal-tar coloring materials used in food, when such materials are not generally recognized by experts as safe, are classified as "food additives" under the Food Additives Amendment of 1958—Public Law 85-929. Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed to be adulterated if the additive is unsafe within the meaning of section 409. Under section 409 the food additive is deemed unsafe unless it and its use, or intended use, conform to a regulation issued by the Secretary announcing the conditions, including the establishment of tolerance limitations, under which the additive may be safely used. Food colors which were in commercial use before January 1, 1958, are allowed a grace period not later than March 6, 1961, for compliance with the provisions of the Food Additives Amendment of 1958. Such "food additive" colors, however, are not subject to any requirement of "batch" certification.

NEED FOR LEGISLATION

The principal reasons which give rise to the need for this legislation may be summarized as follows:

First. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection, in that it does not allow the Secretary of Health, Education, and Welfare to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, the Secretary must ban the use of such a color completely, as not being harmless, if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe. For externally applied drugs and cosmetics, the same principle applies if toxicity appears in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use may be wholly safe.

Prior to delisting proceedings by the Department of Health, Education, and Welfare there were 19 colors listed for unrestricted use in food, drugs, and cosmetics, 69 colors listed for unrestricted use in drugs and cosmetics, and 30 colors listed for use only in externally applied drugs and cosmetics, a total of 118 straight colors listed for certification. Seven colors have been removed from the food, drug, and cosmetic list and have been relisted for external use in drugs and cosmetic colors, so that we now have 12 food, drug, and cosmetic colors, 69 unrestricted drug and cosmetic colors, and 37 drug and cosmetic colors for external use. The Department has proposed that other colors be removed from listing and certification.

Only last week the Food and Drug Administration announced a tentative decision removing 14 coal-tar colors used principally in lipsticks from the list of permitted colors for unrestricted use in drugs and cosmetics. This decision was based upon an evaluation of evidence presented at a public hearing granted color, lipstick, and drug manufacturers. A final decision on delisting will be made after consideration of any objections which may be filed by the affected parties to the proposed order.

The principle of allowing colors to be used under tolerance limitations was endorsed, in 1956, by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program of the Food and Drug Administration, as indicated by the following excerpt from the committee's report:

This committee feels compelled to indicate that certification of a compound as harmless and suitable for use in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified (report of the National Academy of Sciences-National Research Council Ad Hoc Advisory Committee To Review the Food and Drug Administration's Research Program on Coal-tar Dyes, June 1956).

Second, The theoretically perfect public health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While theoretically, only harmless colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many of the so-called coal-tar colors on the list may in fact be toxic in some concentrations. Yet, the Secretary of Health, Education, and Welfare cannot take a particular color off the list until he establishes its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the established colors would have to be completed—primarily by industry—and during which the Secretary could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

Third. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present there are no provisions for the certification of non-coal-tar colors. There is, moreover, no pretesting requirement for non-coal-tar additives as such, other than food additives.

Fourth. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under

[p. 14357]

the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use—including tolerance limitations and certification requirements—established by the Department of Health, Education, and Welfare.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress in temporary emergency legislation—Public Law 86-2—with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring mature oranges, after previous adoption of the "Safe-for-use" principle in the Food Additives Amendment of 1958—Public Law 85-929. In reporting upon the emergency legislation for citrus red No. 2, this committee said:

> It is specifically provided that the provisions of this bill will become inoperative on August 31, 1961, or before that time if general legislation affecting coloring materials for food is enacted by the Congress. One reason for the time limit is that this emergency legislation, will meet the immediate needs of the citrus industry without permanently engrafting on the basic Food, Drug, and Cosmetic Act a new principle of tolerances for coal-tar colors which is not applicable to foods generally. The expiration date has been so fixed as to allow the Congress ample time to consider the application of this principle to all foods.
>
> It is the intention of the committee as soon as feasible to study amendments to the Federal Food, Drug, and Cosmetic Act dealing with color additives generally, since the need for such legislation has been amply demonstrated to this committee (86th Cong., 1st sess., H. Rept. 88).

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

EXPLANATION OF COMMITTEE BILL

The bill would change existing law in the following major respects:

First. Uniform criteria of admissibility. It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics—other than hair dyes. This would be accomplished by excepting color additives—as defined in the bill—from the term "food additive"; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section—section 706—comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification—or exemption from certification—and making other amendments to the act to mesh with these provisions.

The bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term "coal-tar color." The bill would therefore establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. The lack of consumer protection inherent in the absence of such a requirement was forcefully brought to the attention of Congress by the investigations and recommendations of the House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, the Delaney committee in the 82nd Congress, and by the hearings culminating in the enactment of the Food Additives Amendment of 1958.

Second. Safety-of-use principle. The bill adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use (including maximum tolerance limitations) as are determined to be necessary to assure the safety of such use.

Third. The Delaney anticancer clause. One provision of the bill which aroused considerable controversy in the hearings on this legislation is proposed section 706(b) (5) (B) appearing on page 11, line 8, of the reported bill, and often referred to as the Delaney anticancer clause.

This clause provides that a color additive shall be deemed unsafe and shall not be listed for any use which will or may result in ingestion of all or any part of such additive if the additive is found to induce cancer when ingested by man or animal, or if it is found to induce cancer in man or animal by other tests, not involving ingestion, which are considered to be appropriate for the evaluation of the safety of additives for use in food.

This clause also provides that a color additive shall be deemed unsafe and shall not be listed for any use which will result in ingestion of any part of such additive if, after tests which are appropriate for the evaluation of the safety of the additive for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

A similar anticancer clause is included in the Food Additives Amendment of 1958 to the Federal Food, Drug, and Cosmetic Act—Public Law 85–929.

There are many unknowns about cancer that are yet to be solved. We do know, however, that today cancer is second only to heart disease as a cause of death among the American people. Every year, approximately 250,000 people die of cancer in this country. Approximately 450,000 new cases of cancer are discovered each year. At any given time about 700,000 persons are under treatment for cancer.

Expert testimony before the committee showed that scientific inquiry into the incidence of cancer among certain occupational groups has been traced, in several instances, to specific substances involved in their environment. Laboratory experiments have shown that a number of substances when added to the diet of test animals have produced cancers of various kinds in the test animals. It is this fact—namely, that small quantities of certain materials over a period of time will cause abnormal cell growth in animals—that gave rise to the Delaney anticancer clause in the Food Additives Amendment.

[p. 14358]

Mr. HARRIS. Mr. Speaker, I ask unanimous consent for the immediate consideration of the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions — including maximum tolerances—under which such additives may be safely used.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

The Clerk read the bill, as follows:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this act may be cited as the "Color Additive Amendments of 1959."

* * * * *

Colors or colored articles—when deemed to be adulterated or misbranded foods, drugs, or cosmetics

Food

SEC. 102. (a)(1) Clause (2)(A) of section 402(a), as amended, of such act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive".

(2) Section 402(c), as amended, of such act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)." [p. 14373]

"Changes in cross-references and terminology

'SEC. 105. Such Act is further amended by—

"(a) striking out, in section 301(i) thereof (relating to forgery or unauthorized use of certain identification devices), '404, 406(b), 504, 506, 507, or 604', and inserting in lieu thereof '404, 506, 507, or 706';

"(b)(1) striking out, in clause (3) of section 303(c) (relating to color manufacturer's guarantee), the word 'coal-tar' wherever it appears in such clause, and (2) inserting after the word 'color', wherever it appears in such clause, the word 'additive'; and

"(c) striking out 'harmless coloring' in section 402(d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof 'authorized coloring'.

[p. 14377]

1.10d (3) (c) VOL. 106 (1960), June 30: Senate concurs in House amendment, p. 15133

[No Relevant Discussion on Pertinent Section]

1.10e ANIMAL DRUGS IN FEEDS AMENDMENTS OF 1968

July 13, 1968, P.L. 90–399, §104, 82 Stat. 352

ANIMAL DRUGS IN FEEDS AND RESIDUES THEREOF IN OTHER FOOD

SEC. 104. Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by—

(1) striking out the word "or" before "(iii)" in clause (A) of subparagraph (2) of paragraph (a) and inserting "; or (iv) a new animal drug" after the words "color additive" therein; and

(2) adding before the semicolon following "commodity" at the end of the proviso clause (C) of subparagraph (2) of paragraph (a) the following: "; or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512".

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1.10e (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 875, 90th Cong., 1st Sess. (1967)

ANIMAL DRUG AMENDMENTS OF 1967

OCTOBER 31, 1967.—Committed to the Committee of the Whole House on the state of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 3639]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 3639) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to consolidate certain provisions assuring the safety and effectiveness of new animal drugs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are as follows:

On page 28, strike out lines 9 through 16.

On page 28, line 19, strike out "107" and insert in lieu thereof "106".

On page 29, line 4, strike out "108" and insert in lieu thereof "107".

PRINCIPAL PURPOSE OF THE BILL

The bill would consolidate into one place in the law all of the principal provisions of the Federal Food, Drug, and Cosmetic Act which relate to premarketing clearance of new drugs for administration to animals, either directly or in their feed and water. The bill is supported by the entire animal drug and feed manufacturing industry, by the Department of Health, Education, and Welfare, the Bureau of the Budget, and the Department of Agriculture.

[p. 1]

* * * * * * *

SECTIONS 104–105

These sections make changes in section 402 (adulterated food); 502 (misbranded drugs); and 507 (antibiotics) to reflect the new pattern of regulation of new animal drugs and animal feeds by the new section 512.

[p. 6]

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CHAPTER IV—FOOD

* * * * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

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(2) (A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; [or] (iii) a color additive; *or (iv) a new animal drug)* which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409; *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; *or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512;* or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

(d) If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object: *Provided*, That this clause shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts; or

(3) bears or contains any nonnutritive substance: *Provided*, That this clause shall not apply to a safe nonnutritive [p. 18] substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this Act: *And provided further*, That the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

[p. 19]

1.10e (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 1308, 90th Cong., 2d Sess. (1968)

ANIMAL DRUG AMENDMENTS OF 1968

JUNE 21 (legislative day, JUNE 19), 1968.—Ordered to be printed

Mr. HILL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H.R. 3639]

The Committee on Labor and Public Welfare, to which was referred the bill (H.R. 3639) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to consolidate certain provisions assuring the safety and effectiveness of new animal drugs, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

PRINCIPAL PURPOSE OF THE BILL

The bill would consolidate into one place in the law all of the principal provisions of the Federal Food, Drug, and Cosmetic Act which relate to premarketing clearance of new drugs for administration to animals, either directly or in their feed and water. The bill is supported by the entire animal drug and feed manufacturing industry, by the Department of Health, Education, and Welfare, the Bureau of the Budget, and the Department of Agriculture.

The enactment of this legislation would merely consolidate provisions under existing law and would in no way weaken the authorities of the Food and Drug Administration with respect to the regulation of new animal drugs.

NEED FOR LEGISLATION

In many cases, the requirements for clearance of new drugs for administration to animals are more complicated than the clearance procedures for new human drugs. These complexities have in some

[p. 1]

instances led to long delays in the clearance of new animal drugs, and the purpose of the bill is to provide a single procedure for clearance of these drugs.

Under existing law, a drug which is intended for use in animal feeds is regulated both as a new drug under section 505 of the Federal Food, Drug, and Cosmetic Act, and as a food additive under section 409 of that act. This means that the drug must be cleared under the procedures of both sections of the law. Where the product is a combination of drugs containing a certifiable antibiotic, the product is regulated under the antibiotic section of the Federal Food, Drug, and Cosmetic Act (sec. 507).

By consolidating into one place in the law all of the provisions providing for regulation of these drugs, clearances should be expedited, with resulting decreases in costs, and consequent encouragement for the development by manufacturers of new drugs for use in animals.

USE OF ANIMAL DRUGS

In the past 15 years the animal feed industry in the United States has been virtually revolutionized through the use of drugs and other additives in the feed of animals. Drugs are used to promote growth and combat disease, and as a result of the increasing use, animals today add more meat per pound of feed in a much shorter time than has ever been true in the past. This means that the price of meat and poultry is much less than it otherwise would be. For example, in 1950 broiler production was about 630 million birds whereas in 1965 it was well over 2 billion. The average retail price of broilers has dropped from 57 cents a pound in 1950 to approximately 39 cents today. This results from two factors. First, a few years ago, broiler producers had 15 to 20 percent of their chicks die before they reached maturity whereas today it is not unusual for broiler producers to raise 99 to 100 percent of the chicks started.

In addition, broilers are ready for market weeks earlier today than a few years ago, and they consume less feed per pound of added body weight than was true a few years ago. Similar developments have taken place in the beef producing industry and in the production of swine, lambs, and other animals.

The American consumer, it is widely acknowledged, is the best fed in the world. He is so in very large part because the animal health industry has provided the farmer with the resources to maintain and enlarge herds and flocks of meat- and milk-producing animals. Yet the farmer even today suffers enormous losses in disease, parasites, and insects, losses estimated by the Department of Agriculture at $2.8 billion per year. These losses not only reduce farm income, but by reducing the supply of food, affect the availability of meat, poultry, eggs, and milk and increase the cost of the basic foods to the consumer.

Each delay in the clearance of safe and effective products for animal health perpetuates these losses. Every duplication of unnecessary controls adds to the ultimate cost of providing food for the consumer. Every lack of administrative coordination adds needlessly to the time required to provide the farmer with the resources he needs to feed an ever-growing population.

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At the hearing held on H.R. 3639 and in similar hearings held on earlier proposals, there was ample testimony that the existing provisions of the Federal Food, Drug, and Cosmetic Act, because they were designed primarily to be applicable to drugs and food additives for human consumption, created problems in the administration of the act with respect to animal health products. Some of the delay and lack of coordination has been cured administratively by the Food and Drug Administration. On the basis of hearings, however, it seems quite apparent that this coordination should be fostered legislatively by consolidating into one section of the act, in a coordinated fashion, under a simplified procedure, the various provisions and requirements applicable to animal-health products.

H.R. 3639, as reported by the committee, is intended to do just this: Coordinate and consolidate the applicable provisions governing drugs, feed additives, and antibiotics for animal use into one logical coordinated system that, without removing any of the stringent requirements for premarketing clearances, would assist this clearance and the subsequent use of animal-health products.

This bill draws a distinction between new animal drugs and animal feed bearing or containing a new animal drug, and subjects them to different regulations and procedures.

Section 102 of this bill, which amends section 201 of the Federal Food, Drug, and Cosmetic Act, in effect defines the term "new animal drug," as used in the bill, as including any "new drug" intended for use in animal feed but not including such animal feed. "Animal feed" is defined as "an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal." Thus, under this legislation, the term "animal feed" encompasses all categories of animal feed intended for use as a substantial source of nutrients in the diet of the animal, including complete feed, feed additive supplements, and feed additive concentrates, as distinguished from so-called feed additive premixes. An animal feed bearing or containing a new animal drug will be subject to the provisions of proposed new section 512(m) as contained in this bill. On the other hand, a feed additive "premix" —which is defined by present regulations (21 CFR 121.200) as an article that must be diluted in a ratio of 1 to 100 pounds per ton for safe use in a feed additive concentrate or supplement or in a complete feed—is, if it contains a new animal drug, itself classifiable as a "new animal drug" under the bill as distinguished from an "animal feed." Such a premix is subject to the provisions of proposed new section 512(b) as embodied in this bill.

AMENDMENT

As passed by the House of Representatives, H.R. 3639 would have permitted the export of new animal drugs, or animal feeds bearing or containing new animal drugs, determined to be unsafe within the meaning of the proposed section 512 of the Federal Food, Drug, and Cosmetic Act. At the request of the Department of Health, Education, and Welfare, this committee has adopted an amendment to section 801(d) of the act that would prevent the export of such animal drugs and such animal feeds. [p. 3]

Under existing law, new animal drugs may not be exported to foreign countries unless the drugs comply fully with the requirements of the U.S. law.

The purpose of the committee amendment is to preserve, essentially, the status quo with respect to the export exemption. Except for an extremely narrow category of antibotics that are intended for direct administration to animals and have not been exempted from the batch-by-batch certification requirement of the present act (sec. 507), all the drugs which under the bill would be known as new animal drugs, and also all animal feeds medicated therewith, at present fall within the definition of "new drugs" and as such are not within the scope of the export exemption (sec. 801 (d)) of the Food and Drug Act and must meet domestic standards insofar as these apply. (It should be noted in this connection that, under the terms of the bill, the requirement of the bill that the manufacturer or distributor of a new animal drug for use in the manufacture of feed obtain from the consignee of the drug a statement that he is, or will ship only to, the holder of an approved animal feed application applies only if the drug is for use in the manufacture of feed in a State, and hence does not apply to exports of these drugs for use in feed manufacture in foreign countries.)

HEARINGS

Hearings on H.R. 3639 were held on May 24, 1968, by the Subcommittee on Health of the Labor and Public Welfare Committee.

The Department of Health, Education, and Welfare recommended enactment of the legislation with the amendment relating to the export of new animal drugs adopted by the committee. The enactment of H.R. 3639 was also endorsed by the Animal Health Institute, the Animal Veterinary Medical Association, and the American Feed Manufacturers Association.

The cost

The Department of Health, Education, and Welfare advises this committee that the enactment of H.R. 3639 would entail no additional cost for its administration.

SECTION-BY-SECTION ANALYSIS

The first section of the bill contains a short title.

[p. 4]

Sections 104–105

These sections make changes in sections 402 (adulterated food); 502 (misbranded drugs); and 507 (antibiotics) to reflect the new pattern of regulation of new animal drugs and animal feeds by the new section 512.

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as

[p. 6]

reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

[p. 7]

SEC. 201.

* * * * * * *

(w) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effective-

ness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 25, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; or

(3) which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 512(n), is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug.

(x) The term "animal feed", as used in paragraph (w) of this section, in section 512, and in provisions of this Act referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

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[p. 8]

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

* * * * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2) (A) if it bears or contains any added poisonous or added deleterious substance other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; [or] (iii) a color additive; *or (iv) a new animal drug)* which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409; *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural com- [p. 9] modity; *or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512;* or

* * * * * * *

[p. 10]

1.10e (3) CONGRESSIONAL RECORD

1.10e (3) (a) VOL. 113 (1967), Nov. 6: Amended and passed House, p. 31291

Mr. STAGGERS. Mr. Speaker, this bill will assemble into one place in the law all of the major provisions of the Food and Drug Act which relate to drugs for administration to animals either directly or in their feed and water.

Its principal benefits to the drug and feed industry will be to provide for regulation of these drugs through legislation separate from legislation related to human drugs so that in the event of future legislation increasing controls over human drugs, these increased controls will not automatically apply to animal drugs as would be the case under existing law.

EXISTING LAW

The definition of "drug" in existing law is very broad and covers every substance which is intended to affect the structure or functions of the body of man or any other animal and, therefore, includes not only all substances for direct administration to animals to promote health, but also includes all feeds which contain drugs. This makes every feed manufacturer in the United States who mixes any drugs into his product automatically a "drug manufacturer" subject to stringent regulation.

Similarly, the term "food additive" is very broadly defined in the Food and Drug Act, so that drugs which are used in the manufacture of animal feed are also "food additives" as defined.

The result of the foregoing means that every manufacturer of drugs for use in animal feeds and every feed manufacturer who uses such drugs is subject to regulation under the Food Additives Amendment—section 409 of the Food and Drug Act—and the new drug section of the law—section 505 of the Food and Drug Act.

Since a substantial number of animal feeds also contain antibiotics, feed manufacturers are subject to regulations under the antibiotic section of the Food and Drug Act—section 507—with respect to certified antibiotics.

A number of years ago, the manufacturers involved were required to submit two separate applications to FDA for clearance of animal feeds containing any drug. Through administrative action, FDA has simplified the procedure so that only one application is required to be filed today and there is better coordination between the three divisions of FDA which pass on applications for the use of drugs in animal feeds—the Food Additive Division, the New Drug Division, and the Antibiotic Division.

A Bureau of Veterinary Medicine has been established and the very substantial delays in FDA action which formerly plagued the industry have been cut down considerably.

[p. 31291]

1.10e (3) (b) VOL. 114 (1968), June 24: Amended and passed Senate, p. 18424

[No Relevant Discussion on Pertinent Section]

1.10e (3) (c) VOL. 114 (1968), July 2: House concurs in Senate amendments, pp. 19713–19714

AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO CONSOLIDATE CERTAIN PROVISIONS ASSURING SAFETY AND EFFECTIVENESS OF NEW ANIMAL DRUGS

Mr. STAGGERS. Mr. Speaker, I ask unanimous consent to take from the Speaker's desk the bill (H.R. 3639) to protect the public health by amending the Federal Food, Drug and Cosmetic Act to consolidate certain provisions assuring the safety and effectiveness of new animal drugs, and for other purposes, with Senate amendments thereto, and concur in the Senate amendments.

The Clerk read the title of the bill.

The Clerk read the Senate amendments, as follows:

Page 1, line 4, strike out "1967.'" and insert "1968.'"

Page 28, after line 8, insert:

"ANIMAL DRUGS FOR EXPORT

"SEC. 106. Section 801(d) of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by adding at the end thereof the following: 'Nothing in this subsection shall authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 of this Act.'"

Page 28, line 11, strike out "106." and insert "107."

Page 28, line 21, strike out "107." and insert "108."

The SPEAKER. Is there objection to the request of the gentleman from West Virginia?

Mr. SPRINGER. Mr. Speaker, reserving the right to object—and I shall not object—I think there ought to be some brief explanation.

Mr. STAGGERS. Mr. Speaker, this motion to concur in the Senate amendment has been cleared with the gentleman from Illinois [Mr. SPRINGER] and with the ranking members of the Subcommittee on Public Health and Welfare.

The amendment of the Senate merely restores the bill to the same status it had when originally introduced in the House. During the consideration of the bill by our Subcommittee on Public Health and Welfare, an amendment was suggested providing some loosening of the requirements of the Food and Drug Act with respect to exports [p. 19713] of animal feeds. When the bill was considered in the Senate, this was the only controversial feature of it, so the Senate agreed to an amendment which leaves existing law with respect to exports exactly the way it is today.

In other words, Mr. Speaker, this bill is primarily a consolidation of existing law relating to animal drugs and animal feeds bearing or containing new animal drugs. The Senate amendment leaves existing law as it currently stands.

Section 106 which amends section 801 (d) of the act will in no way preclude export of animal feed containing a new animal drug which has been produced by a feed manufacturer in accordance with section 512(m) of the act, since its safety will have already been determined. The Senate report makes it clear—page 3—that animal feed which contains a new animal drug is to be distinguished from a new animal drug and is to be regulated under the provisions of section 512(m). The second sentence of section 512(a)(1) which makes reference to a consignee having an approved application applies only to new animal drugs and has no applicability to animal feed containing a new animal drug which has been incorporated into the feed in accordance with the provisions of section 512(m).

Mr. Speaker, I urge the adoption of the amendment.

Mr. SPRINGER. Mr. Speaker, I withdraw my reservation of objection.

Mr. NELSEN. Mr. Speaker, I ask unanimous consent to extend my remarks at this point in the RECORD.

The SPEAKER. Is there objection to the request of the gentleman from Minnesota?

There was no objection.

Mr. NELSEN. Mr. Speaker, all of us who worked so hard and long on this proposal to facilitate the handling of animal drug applications by the FDS are indeed very happy to see this bill finally passed by the Congress.

I might comment on some clarifying language which appears in the Senate report. Section 106 which amends section 801(d) of the act will in no way preclude the export of animal feed containing a new animal drug which has been produced by a feed manufacturer in accordance with section 512(m) of the act, since its safety will have already been determined. The Senate report makes it clear—page 3—that animal feed which contains a new animal drug is to be distinguished from a new animal drug and is to be regulated under the provisions of section 512(m). The second sentence of section 512(a)(1) which makes reference to a consignee having an approved application applies only to new animal drugs and has no applicability to animal feed containing a new animal drug which has been incorporated into the feed in accordance with the provisions of section 512(m).

The SPEAKER. Is there objection to the request of the gentleman from West Virginia?

There was no objection.

The Senate amendments were concurred in.

A motion to reconsider was laid on the table.

[p. 19714]

1.11 LISTINGS AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS—UNSAFE COLOR ADDITIVES AS AMENDED

21 U.S.C. §376(b) (5) (D) (1970)

[Referred to in 21 U.S.C. §346a (g)]

LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS—UNSAFE COLOR ADDITIVES

21 § 376

(b) * * * * * * * * * *

(5) * * * * * * * * * *

(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of any advisory committee established under this chapter, while attending conferences or meetings of their committees or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS–18 of the General Schedule, including traveltime; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of Title 5 for persons in the Government service employed intermittently. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

June 25, 1938, c. 675, § 706, 52 Stat. 1058; July 12, 1960, Pub.L. 86–618, Title I, § 103(b), 74 Stat. 399; and amended Oct. 10, 1962, Pub.L. 87–781, Title I, § 104(f) (2), 76 Stat. 785; Oct. 30, 1970, Pub.L. 91–515, Title VI, § 601(d) (2), 84 Stat. 1311.

1.11a FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS OF 1962

October 10, 1962, P.L. 87–781, Title I, §104(f) (2), 76 Stat. 785

SEC. 104 (f) (2) Subparagraph (B) of paragraph (5) of section 706 (b) of such Act (21 U.S.C. 376 (b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: "*Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

1.11a (1) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 1744, 87th Cong., 2d Sess. (1962)

DRUG INDUSTRY ACT OF 1962

JULY 19, 1962.—Ordered to be printed

Mr. EASTLAND, from the Committee on the Judiciary, submitted the following

REPORT

together with

INDIVIDUAL VIEWS

[To accompany S. 1552]

The Committee on the Judiciary, to which was referred the bill (S. 1552) to amend and supplement the antitrust laws with respect to the manufacture and distribution of drugs, and for other purposes, having considered the same, reports favorably thereon, with an amendment in the nature of a substitute, and recommends that the bill, as amended, do pass.

AMENDMENT

Strike all after the enacting clause and insert in lieu thereof the following:

That the Act may be cited as the "Drug Industry Act of 1962".

* * * * * * *

[p. 1]

PURPOSE

The purpose of the proposed legislation, as amended, is to strengthen and broaden existing laws in the drug field so as to bring about better, safer medicine and to establish a more effective system of enforcement of the drug laws.

The amended bill would help assure a safer and more reliable drug supply for the Nation by requiring registration of all prescription drug manufacturers and more effective inspection of their plants to determine whether such drugs are being manufactured in accordance with the law. In addition, the bill requires the installation and maintenance of acceptable drug manufacturing and control procedures and a premarketing showing that all new drugs are effective—as well as safe—for their intended uses. The bill also would improve the procedures employed in the advance approval of new drugs and would permit the prompt removal from the market of such drugs when new evidence, considered with what was known originally establishes that the drug should not have been cleared for safety in the first instance. The bill would further require drug manufacturers to keep records and report to the Department of Health, Education, and Welfare any indications of adverse effects from a new drug or antibiotic and provide for the advance testing and certification as to both safety and effectiveness of all antibiotics—not just the few now covered by such procedures. The bill includes basic improvements, in terms of simplification and usefulness, of drug nomenclature to eliminate confusion as to the identity and composition of drugs. Finally, the bill makes provision for information on drugs to be more readily available to physicians and the general public. In short, the purpose of this bill, as amended, is to strengthen the laws designed to keep unfit drugs off the market in the first instance and speed their removal should they reach the market.

[p. 8]

1.11a (2) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 2464, 87th Cong., 2d Sess. (1962)

DRUG AMENDMENTS OF 1962

SEPTEMBER 22, 1962.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. HARRIS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 11581]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 11581) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are as follows:

The amendment to the text strikes out all of the bill after the enacting clause and inserts in lieu thereof a substitute which appears in the reported bill in italic type. The substitute text is also printed in appendix C.

The other amendment modifies the title of the bill to make it conform to the changes made by the amendment to the text.

PURPOSE OF LEGISLATION

It is the principal purpose of the legislation better to protect the public health by imposing additional requirements and improving procedures in connection with—

1. Controls of manufacture of drugs to assure that manufacturing methods are in conformity with current good manufacturing practice;
2. Requirement that new drugs be shown to be effective as well as safe;
3. Keeping of records and furnishing of reports in connection with safety and effectiveness of new drugs and antibiotics; [p. 1]

4. Procedures to be followed in the testing of investigational drugs, including patients' consent;
5. Agency procedures to be followed in approving new drugs;
6. Summary suspension of new drugs where there is an imminent hazard to public health;
7. Withdrawal of new drugs when their safety or effectiveness is no longer assured;
8. Certification of all antibiotics for man (present law requires only certification of certain antibiotics);
9. Factory inspection of establishments manufacturing prescription drugs;
10. Manufacturers making available adequate information concerning safety and effectiveness of drugs advertised to physicians.
11. Simplifying drug nomenclature.

ADEQUATE MANUFACTURING CONTROLS FOR ALL DRUGS

The manufacturing of drugs is a business that requires highly qualified and trained personnel, and special laboratory and other facilities and most careful internal manufacturing, packaging, and labeling controls. These requirements are necessary to the assurance that the drugs will be safe for the user and will have, and so far as possible retain, the identity, strength, quality, purity, and effectiveness that they purport to have.

Except in the case of those drugs for which the Federal Food, Drug, and Cosmetic Act requires premarketing clearance (i.e., new drugs, certain antibiotics, and insulin) and except for drugs prepared or held under insanitary conditions, nothing can be done under the present act if these essential requirements demanded by good manufacturing practice are not met, until a particular shipment of drugs is marketed and the Food and Drug Administration can prove that the drug itself is different. This is not adequate assurance of consumer protection. People with inadequate experience, equipment, and technical competence can, and do, enter the business of making drugs.

Section 101 of the reported bill would amend section 501 (a) (1) of the Federal Food, Drug, and Cosmetic Act to deem a drug to be adulterated if the methods, facilities, or controls used in its manufacture, processing, packaging, or holding fail to conform to, or are not operated or administered in conformity with, good manufacturing practices as determined in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare which are designed to assure that the drug is safe and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess. The phrase "operated or administered in conformity with current good manufacturing practice" encompasses key technical and professional personnel responsible for the safety of the drug, and its identity, strength, quality, and purity characteristics.

The promulgation of these regulations would be subject to opportunity for hearing and judicial review. Thus, legal action could be brought against firms failing to abide by these standards and against the products they ship. [p. 2]

NEW DRUG CLEARANCE PROCEDURE

Section 104 makes a number of important changes in the new drug procedures.

Section 104 (a) eliminates the provisions of existing law under which a new-drug application becomes effective automatically at the expiration of 60 or 180 days if the Department does not take positive action to prevent this. Under the bill, a new-drug application is not effective unless it has affirmative approval both for safety and effectiveness.

In section 104 (b) the committee revised the time schedule for action on new-drug applications. The Secretary has 180 days, after filing of a new drug application, to approve it or give the applicant notice of an opportunity for hearing. The applicant has 30 days after notice to accept the opportunity for hearing, the hearing must start within 90 days unless a different date is agreed upon, and it must proceed on an expedited basis. The Secretary has 90 days, after completion of the hearing, to issue his order.

Section 104 (c) provides that any order refusing, revoking, or suspending approval of a new-drug application shall be withdrawn by the Secretary when he finds that the facts so require.

Section 104 (d) changes the judicial review over the denial or withdrawal of approval of a new drug from the district courts to the U.S. courts of appeals. This is a review, on the record, of administrative action, which more appropriately belongs in the courts of [p. 10] appeals. And this procedure is the same as the judicial review under other sections of the Federal Food, Drug, and Cosmetic Act. Pending appeals taken prior to enactment of the bill would not be affected.

Section 104 (e) contains conforming amendments in sections 301 and 503 (b) of the Federal Food, Drug, and Cosmetic Act to reflect the fact that affirmative approval, rather than automatic effective dates, has been required for new drugs.

Section 104 (f) amends sections 409(c) and 706(d) of the Federal Food, Drug, and Cosmetic Act, by making the anticancer clause of the Food Additives Amendment of 1958 and the Color Additive Amendment of 1960 inapplicable to chemicals, such as veterinary drugs, when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food, such as milk or eggs, yielded by or derived from the living animal.

[p. 11]

New Drug Clearance Procedure

Sec. 104 (a) Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335(a)) is amended to read as follows: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug."

(b) Section 505 (c) of such Act (21 U.C. 355 (c)) is amended to read as follows:

[p. 59]

"(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

> ***"(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or***
>
> ***"(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after such hearing is completed."***

(c) Section 505 (f) of such Act (21 U.S.C. 355 (f)) is amended to read as follows:

"(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate."

(d) (1) The first four sentences of section 505 (h) of such Act (21 U.S.C. 355 (h)) are amended to read as follows:

"(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order."

(2) The ninth sentence of such section 505 (h) is amended to read as follows: "The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code."

(3) The amendments made by this subsection shall not apply to any appeal taken prior to the date of enactment of this Act.

(e) (1) Section 301 (l) of such Act (21 U.S.C. 331 (l)) is amended by (1) inserting "approval of" before "an application", and (2) striking out "effective" and inserting in lieu thereof "in effect".

(2) Clause (C) of section 503 (b) (1) of such Act (21 U.S.C. 353 (b) (1)) is amended by striking out "effective" and inserting in lieu thereof "approved".

(f) (1) Clause (A) of paragraph (3) of section 409 (c) of such Act (21 U.S.C. 348 (c)) is amended by inserting before the semicolon at the end thereof the following: ", except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding

specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended and (ii) that no residue of the additive will be found by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal" [p. 60]

* * * * * * *

(2) Subparagraph (B) of paragraph (5) of section 706 (b) of such Act (21 U.S.C. 376 (b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: "Provided, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal". [p. 61]

1.11a (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 2526, 87th Cong., 2d Sess. (1962)

DRUG AMENDMENTS OF 1962

OCTOBER 3, 1962.—Ordered to be printed

Mr. ROBERTS of Alabama, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 1552]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 1552) to amend and supplement the laws with respect to the manufacture and distribution of drugs, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Drug Amendments of 1962."

* * * * * * *

[p. 1]

New Drug Clearance Procedure

Sec. 104. (a) Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)), is amended to read as follows:

"(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug."

(b) Section 505(c) of such Act (21 U.S.C. 355(c)) is amended to read as follows:

"(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

[p. 5]

"(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

"(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs."

(c) Section 505(f) of such Act (21 U.S.C. 355(f)) is amended to read as follows:

"(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and

shall approve such application or reinstate such approval, as may be appropriate."

(d)(1) The first four sentences of section 505(h) of such Act (21 U.S.C. 355(h)) are amended to read as follows: "An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order."

(2) The ninth sentence of such section 505(h) is amended to read as follows: "The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code."

(3) The amendments made by this subsection shall not apply to any appeal taken prior to the date of enactment of this Act.

(e) (1) Section 301(l) of such Act (21 U.S.C. 331(l)) is amended by (1) inserting "approval of" before "an application", and (2) striking out "effective" and inserting in lieu thereof "in effect".

(2) Clause (C) of section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)) is amended by striking out "effective" and inserting in lieu thereof "approved".

(f)(1) Clause (A) of paragraph (3) of section 409(c) of such Act (21 U.S.C. 348(c)) is amended by inserting before the semicolon at the end thereof the following: ", except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for

[p. 6]

which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal".

(2) Subparagraph (B) of paragraph (5) of section 706(b) of such Act (21 U.S.C. 376(b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: "Provided, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

[p. 7]

ANIMAL FEED

The House amendment contained a provision amending the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by

[p. 20]

making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal.

The Senate bill did not contain this provision.

The conference substitute adopts the House provision in this respect.

[p. 21]

1.11a (4) CONGRESSIONAL RECORD, VOL. 108 (1962)

1.11a (4) (a) Aug. 23: Amended and passed Senate, p. 17422
[No Relevant Discussion on Pertinent Section]

1.11a (4) (b) Sept. 27: Discharged, amended and passed House, pp. 21052, 21083, 21097

Mr. HARRIS.

* * * * *

ANIMAL FEED

The committee amended the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds first, that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended; and second, that no residue of the additive will be found—by methods of examination prescribed or approved by the Secretary by regulations—in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal.

[p. 21052]

Mrs. SULLIVAN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mrs. SULLIVAN: On page 46, line 4, strike out lines 4 through 19.

Mrs. SULLIVAN. Mr. Chairman, my previous amendment was directed at a proposal to allow more feed manufacturers to use a cancer-inducing substance in feed for meat animals. There is some economic justification for using stilbestrol in fattening cattle, if it can be proved completely safe—as it has not been so far. But farmers can fatten their livestock to market weight much faster and on less feed by using these additives, and therefore, in the absence of overwhelming proof of danger to the consumer from eating meat from such animals, the farm people believe they should have the right to use this additive in feeding livestock.

But, Mr. Chairman, there is no justification—economic or otherwise—for permitting the use of cancer-inducing coloring matter in this feed. The animals, I believe, cannot distinguish colors. But the farm hands apparently can. So the dangerous additive, which must not be fed to the cattle for at least several days before slaughter, to make sure there is no residue in the meat, is identified with coloring matter to differentiate one kind of feed from another.

Now just look what we are getting into here. The feed manufacturers say they have to use colors, which are now prohibited for this use because they can cause cancer. Are we allowing this very potent and very dangerous cancer-inducing substance, stilbestrol, to be handled by farmhands who are unable to read directions on the label or package, and must have special colors used to guide them—colors which are cancer inducing?

Before the color additives act was passed in 1960, I obtained and put in the CONGRESSIONAL RECORD evidence from National Institutes of Health scientists, cancer experts, that there is no such thing as a harmless amount of a cancer-inducing substance as far as humans are concerned.

In this bill—in the section to which I previously offered an amendment—we would let more feed manufacturers use a cancer-inducing substance in animal feed for economic reasons. Now, in this section, we would be saying: put a little more cancer in, for color, to help the farmhand know which sack to use in the final days before slaughter. Are we to believe our farmers are too dumb to handle this material otherwise?

If the man can't read or understand directions, how do we dare trust him with these potent, dangerous, substances, to use the right proportion or amount?

There is no justification for permitting cancer-inducing coloring matter in anything going into our food supply. The Delaney clause prohibits it. Let us uphold that principle. This provision of the bill must come out.

Mr. ROBERTS of Alabama. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, the same arguments that apply with reference to the gentlewoman's other amendment apply to this amendment. The only reason, I suppose, for offering this amendment is that veterinary drugs have been classified both as food additives and as color additives. I repeat that there was no proof before the subcommittee that the use of stilbestrol as presently used under the direction of the Food and Drug Administration has been shown to induce cancer in animals. No residue has been found, no harm to the animal.

The same proposition was before the House a few minutes ago on a similar amendment, and with the additional power of withdrawal contained in the omnibus bill those people who might have some suspicion of this stilbestrol are in a better position than they ever have been before. The Food and Drug Administration testified in favor of this amendment. It has been asked for by Secretary Ribicoff when he was head of the Department of Health, Education, and Welfare, also Secretary Flemming. It has been approved by studies made by the American Medical Association and by the National Institutes of Health. I would respectively ask that the House vote "no" on this amendment.

The CHAIRMAN. The question is on the amendment offered by the gentlewoman from Missouri [Mrs. SULLIVAN].

The amendment was rejected.

[p. 21083]

SEC. 104 "(f)(1) Clause (A) of paragraph (3) of section 409(c) of such Act (21 U.S.C. 348(c)) is amended by inserting before the semicolon at the end thereof the folowing: ', except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal'.

"(2) Subparagraph (B) of paragraph (5) of section 706(b) of such Act (21 U.S.C. 376(b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: '*Provided*. That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal'.

[p. 21097]

1.11a (4) (c) Oct. 3: Senate concurred in conference report, pp. 22039, 22053

Mr. KEFAUVER.

* * * * *

The conferees also accepted a House provision which would correct a needless and unintentional inequity in the application of the food additive anticancer proviso to additives for animal feed, while preserving in its full vigor the consumer protection now afforded by that provision.

The provision stipulates that the anticancer proviso of existing law shall not apply with respect to the use of a substance—for example, a veterinary drug—as an ingredient of feed for animals which are raised for food production, if the Secretary finds, first, that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended; and, second, that no residue of the additive will be found in any edible portion of such animals after slaughter or in any food product of the living animal—such as milk or eggs.

Another amendment would similarly amend the basic act—which is the corresponding anticancer clause contained in the color additive amendment of 1960 to the basic act.

It should be emphasized that where a new drug is involved in these fields and subsequent information and new evidence raise a question as to its safety, it can be withdrawn under the new withdrawal and suspension powers provided for in section 102 of the bill.

[p. 22039]

Mr. HUMPHREY.

* * * *

VETERINARY DRUG PROVISION

I am particularly gratified to note that the conferees have accepted the House amendment clarifying the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act, by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals, if—I emphasize—if, the Secretary finds:

First. That under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and

Second. That no residue of the additive will be found—by methods of examination prescribed or approved by the Secretary by regulations—in any edible portion of the animal after slaughter or in any food, such as milk or eggs, yielded by or derived from the living animal.

This corrects a needless and unintentional inequity in the application of the food additive anticancer proviso to additives for animal feed, while preserving in its full vigor the consumer protection now afforded by that provision.

I reiterate—consumer protection is assured. [p. 22053]

1.11a (4) (d) Oct. 4: House concurs in conference report, p. 22321

[Conference Report excerpt]

ANIMAL FEED

The House amendment contained a provision amending the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal.

The Senate bill did not contain this provision.

The conference substitute adopts the House provision in this respect.

[p. 22321]

1.11b NATIONAL ADVISORY COUNCIL AMENDMENTS

October 30, 1970, P.L. 91-515, Title VI, §601(d) (2), 84 Stat. 1311

TITLE VI—MISCELLANEOUS

NATIONAL ADVISORY COUNCIL

SEC. 601.

* * * * * * *

[p. 1310]

(d) (1) Subsection (g) of section 408 of the Food, Drug, and Cosmetic Act is amended by striking out "as compensation for their services a reasonable per diem, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence," after "shall receive" and by inserting in lieu thereof "compensation and travel expenses in accordance with subsection (b) (5) (D) of section 706."

(2) Subparagraph (D) of paragraph (5) of subsection (b) of section 706 of such Act is amended by striking out the third sentence thereof and by inserting in lieu thereof the following new sentence: "Members of any advisory committee established under this Act, while attending conferences or meetings of their committees or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS-18 of the General Schedule, including travel time; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5 of the United

[p. 1311]

1.11b (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 91–1297, 91st Cong., 2d Sess. (1970)

HEART DISEASE, CANCER, STROKE, AND KIDNEY DISEASE AMENDMENTS OF 1970

JULY 13, 1970.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 17570]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 17570) to amend title IX of the Public Health Service Act so as to extend and improve the existing program relating to education, research, training, and demonstrations in the fields of heart disease, cancer, stroke, and other major diseases and conditions, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are as follows:

[p 1]

PRINCIPAL PURPOSE OF THE BILL

The bill as reported by the committee would extend for 3 years the existing program known as regional medical programs, under which grants are made for local based programs designed to improve the diagnosis, care, and treatment of heart disease, cancer, and stroke. The legislation would also expand the coverage of the program to cover kidney disease, and would make a number of relatively minor modifications in the program which experience has shown to be desirable.

[p. 3]

* * * * * *

[p. 4]

[No Relevant Discussion on Pertinent Section]

1.11b (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 91-1090, 91st Cong., 2d Sess. (1970)

THE HEALTH SERVICES IMPROVEMENT ACT OF 1970

AUGUST 11, 1970.—Ordered to be printed

Mr. YARBOROUGH, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany S. 3355]

The Committee on Labor and Public Welfare, to which was referred the bills (S. 3355 and related bills) to amend titles III and IX of the Public Health Service Act so as to revise, extend, and improve the programs of research, investigation, education, training and demonstrations authorized thereunder, and for other purposes having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

SUMMARY

S. 3355 would extend for five years (fiscal year 1971 through fiscal year 1975) certain of the authorities under titles III and IX of the Public Health Service Act.

The bill would:

1. extend and improve the Regional Medical Programs authority (Title IX).
2. extend and improve the Comprehensive Health Planning and Services authority (section 314 of title III).
3. extend and improve the authority for the National Center for Health Services Research and Development (section 304 of title III).
4. improve the authority for the National Center for Health Statistics (section 305 of title III).
5. permit for the joint administration of projects involving more than one of the above mentioned authorities with the exception of section 305 (section 310a of title III).
6. require that the Secretary of HEW submit an annual report concerning the effectiveness of these programs (section 310b of title III).
7. create a National Council on Health Policy in the Executive

Office of the President to conduct studies, research, and investigations to set goals for a national health policy for the United States.

8. enable the Secretary of HEW to authorize carriers participating in Federal health benefit programs for Federal employees to issue contracts for prepaid group practice health services to any person, whether or not such persons are Federal employees. [p. 2]

1.11b (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 91–1590, 91st Cong., 2d Sess. (1970)

REGIONAL MEDICAL PROGRAMS AND COMPREHENSIVE HEALTH PLANNING AND SERVICES ACT OF 1970

OCTOBER 8, 1970.—Ordered to be printed

Mr. STAGGERS, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany H.R. 17570]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 17570) to amend title IX of the Public Health Service Act so as to extend and improve the existing program relating to education, research, training, and demonstrations in the fields of heart disease, cancer, stroke, and other related diseases, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment insert the following: [p. 1]

* * * * * * *

TITLE VI—MISCELLANEOUS

NATIONAL ADVISORY COUNCIL

SEC. 601. *(a)(1) Sections 217(b), 432(a), 443(b), and 703(c) of the Public Health Service Act are amended by inserting "or committees" after "councils" wherever it appears therein.*

(2) Sections 431, 432(b), 433, 443, and 452 of such Act are

amended by inserting "or committee" after "council" wherever it appears therein.

(3) Subsections (b) and (c) of section 222 of such Act are amended by inserting "council or" before "committee" wherever it appears therein.

(4) Such section is further amended by inserting in the heading thereof "COUNCILS OR" before "COMMITTEES".

(b)(1) Subsection (c) of section 208 of the Public Health Service Act is amended to read:

"(c) Members of the National Advisory Health Council and members of other national advisory or review councils or committees established under this Act, including members of the Technical Electronic Product Radiation Safety Standards Committee and the Board of Regents of the National Library of Medicine, but excluding ex officio members, while attending conferences or meetings of their respective councils or committees or while otherwise serving at the request of the Secretary, shall be entitled to [p. 14] *receive compensation at rates to be fixed by the Secretary, but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS–18 of the General Schedule, including travel time; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5 of the United States Code for persons in the Government service employed intermittently."*

(2) The second sentence of subsection (d) of section 306, the second sentence of subsection (d) of section 307, the first sentence of paragraph (2) of subsection (f) of section 358, subsection (d) of section (373), subsection (e) of section 641, subsection (d) of section 373, subsection (e) of section 641, subsection (d) of section 703, subsection (d) of section 725, subsection (d) of section 774, subsection (c) of section 841, and subsection (c) of section 905 of such Act are deleted.

(3) Paragraph (2) of subsection (f) of section 358 is further amended by striking out "under this subsection" in the second sentence thereof and by inserting in lieu thereof "to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 208 of this Act".

(4) Subsection (d) of section 905 of such Act is redesigned as subsection (c).

(c)(1) Subsection (a) of section 222 of such Act is amended to read:

"(a) The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, from time to time, appoint such advisory councils or committees (in addition to those authorized to be established under other provisions of law), for such periods of time, as he deems desirable with such period commencing on a date specified by the Secretary for the purpose of advising him in connection with any of his functions."

(2) Subsection (c) of such section is amended by inserting "or programs" after "projects".

(d)(1) Subsection (g) of section 408 of the Food, Drug, and Cosmetic Act is amended by striking out "as compensation for their services a reasonable per diem, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence." after "shall receive" and by inserting in lieu thereof "compensation and travel expenses in accordance with subsection (b) (5) (D) of section 706."

(2) Subparagraph (D) of paragraph (5) of subsection (b) of section 706 of such Act is amended by striking out the third sentence thereof and by inserting in lieu thereof the following new sentence: "Members of any advisory committee established under this Act, while attending conferences or meetings of their committees or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS–18 of the General Schedule, including traveling time; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title (5) of the United States Code for persons in the Government service employed intermittently."

[p. 15]

COMPENSATION OF ADVISORY COUNCIL MEMBERS, ETC.

The Senate amendment contained a provision not in the House bill which would amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to provide uniform rules on compensation of advisory council members and to authorize committees to be established where there is authority to establish advisory councils. The conference substitute contains the provision of the Senate amendment. [p. 22]

1.11b (4) CONGRESSIONAL RECORD, VOL. 116 (1970)

1.11b (4) (a) Aug. 12: Considered and passed House, p. 28532

[No Relevant Discussion on Pertinent Section]

1.11b (4) (b) Sept. 9: Considered and passed Senate, p. 31019

Mr. JAVITS.

* * * * *

[Sec. 104(f)]

"(2) Subparagraph (D) of paragraph (5) of subsection (b) of section 706 of such Act is amended by striking out the third sentence thereof and by inserting in lieu thereof the following new sentence:

" 'Members of any advisory committee established under this Act while attending conferences or meetings of their committees or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but not exceeding the maximum rate specified at the time of such service for grade GS-18 in section 5332 of title 5, United States Code, including travel time; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5 of the Administrative Expenses Act of 1946 (6 U.S.C. 73b-2) for persons in the Government service employed intermittently.' "

Mr. JAVITS. Mr. President, this is exactly the amendment offered by the Senator from Texas (Mr. YARBOROUGH). It relates to compensation of members of the Public Health Service Advisory Council and committees which are established under this bill.

Current provisions of the PHS Act relating to compensation of members of the Public Health Service advisory councils and committees establish varying and widely disparate rates of remuneration for the members of these various groups. At present, and for no discernible reason, some groups are entitled to less than half of the compensation available to the membership of others. These proposed amendments will permit the establishment of uniform rates of compensation for all members of these councils and committees and will thus insure consistent and equitable treatment. They authorize compensation at rates to be fixed by the Secretary, not to exceed the maximum rate specified at the time of service for grade GS-18. They provide for a uniform method of payment for expenses including per diem in lieu of subsistence as authorized for persons in the Government service employed intermittently. The advisory councils and committees play a major role in the NIH programs and those of other Public Health Service agencies. Equitable treatment of their membership in the manner of compensation is in keeping with the importance of their responsibilities.

Also, the Amendment being submitted is similar to part C of the General Education Provisions Act and represents the administration's effort—which acts here through me, as I am the ranking minority member of the committee—to bring about this degree of uniformity.

Again I express my gratitude to the Senator from Texas (Mr. YARBOROUGH). I hope the Senate will take favorable action on this amendment.

Mr. YARBOROUGH. Mr. President, I congratulate the distinguished Senator from New York. As the ranking minority member of the committee he has had a hand in every health bill that has been passed. He is a leader in this field and his services are invaluable.

We have had a great body of health legislation due to the cooperation of the Senator from New York, as the ranking minority member of the committee, and our side. We would not have had this body of health legislation without the active cooperation of the distinguished Senator, and I thank him for it.

The PRESIDING OFFICER. The question is on agreeing to the amendment of the Senator from New York.

The amendment was agreed to.

[p. 31019]

1.11b (4) (c) Oct. 13: House agrees to conference report, pp. 36589–36591

[No Relevant Discussion on Pertinent Section]

1.11d (4) (d) Oct. 14: Senate agrees to conference report, pp. 36888–36892

[No Relevant Discussion on Pertinent Section]

1.12 REGULATIONS AND HEARINGS—AUTHORITY TO PROMULGATE REGULATIONS

21 U.S.C. §371 (1960)

[Referred to in 21 U.S.C. §346a (k), 15 U.S.C. §1474(a)]

REGULATIONS AND HEARINGS—AUTHORITY TO PROMULGATE REGULATIONS

§ 371.

(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

Regulations for imports and exports

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

Conduct of hearings

(c) Hearings authorized or required by this chapter shall be conducted by the Secretary of Health, Education, and Welfare or such officer or employee as he may designate for the purpose.

Effectiveness of definitions and standards of identity

(d) The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

Procedure for establishment

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall

afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Review of order

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeal for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 346 and 347 of Title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

Copies of records of hearings

(g) A certified copy of the transcript of the record and proceedings under subsection (e) of this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this chapter, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f) of this section. June 25, 1938, c. 675, § 701, 52 Stat. 1055; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, c. 646, § 32, 62 Stat. 991; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Apr. 15, 1954, c. 143, § 2, 68 Stat. 55; Aug. 1, 1956, c. 861, § 2, 70 Stat. 919; Aug. 28, 1958, Pub.L. 85–791, § 21, 72 Stat. 948, July 12, 1960, Pub.L. 86–618, Title I, § 103(a) (4), 74 Stat. 398.

1.12a FEDERAL FOOD, DRUG, AND COSMETIC ACT—REGULATIONS & HEARINGS

June 25, 1938, P.L. 75–717, §701, 52 Stat. 1055

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Agriculture shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business,
[p. 1055]
for a judicial review of such order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Secretary based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order,

with the return of such additional evidence.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f). [p. 1056]

1.12a (1) SENATE COMMITTEE ON COMMERCE

S. REP. No. 91, 75th Cong., 1st Sess. (1937)

FOODS, DRUGS, AND COSMETICS

FEBRUARY 15, 1937.—Ordered to be printed

Mr. COPELAND, from the Committee on Commerce,
submitted the following

REPORT

[To accompany S. 5]

The Committee on Commerce, to whom was referred the bill (S. 5) to prevent the adulteration, misbranding, and false advertisement of food, drugs, devices, and cosmetics, in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, having considered the same, report thereon with certain amendments, and as so amended, recommend that the bill do pass. The amendments are incorporated in the bill as reported.

This bill has been prepared with three basic principles in mind: First, it must not weaken the existing laws; second, it must strengthen and extend that law's protection of the consumer; and, third, it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest.

This bill meets these three principles. It has been prepared after many and extensive conferences with the enforcement agencies of the Government and with representatives of various consumer groups or associations, professional groups, and the industries to be regulated.

Separately called meetings were held with representatives of the food, drug, and cosmetic industries. Letters inviting suggestions were sent to many persons known to be interested in the subject. Several volumes of suggestions have been received from persons in the groups just mentioned. These suggestions have been carefully studied; many of them rejected; some accepted; some accepted in part or in effect. The hearings which have been held by committees of the Senate and House of Representatives on previous bills in former sessions of the Congress have been reviewed and studied to take advantage of the information and discussions contained in them.

[p. 1]

ADVERTISING

1. Prohibits false advertising of food, drugs, therapeutic devices, and cosmetics.

FOODS

2. Provides for the promulgation of standards of identity and a reasonable standard of quality for food. (A standard of quality is authorized by the present law for canned food only.)

3. Requires the labeling of unstandardized food to disclose the ingredients by name.

4. Prohibits traffic in food which is dangerous to health. (The present law permits regulation of dangerous food only in the event that the poison is added.)

5. Prohibits addition of poison. If it cannot be avoided in pro-

duction or manufacture, when it reaches the consumer the product must be safe for human use.

6. Eliminates the "distinctive name" proviso of the existing law under which the sale of products, the labels of which are misleading, are now permitted sale.

7. Requires fully informative labeling of infant and invalid food.

8. Requires label declaration of artificial colors and artificial flavors in food.

9. Forbids traffic in confectionery containing metallic trinkets and other inedible substances which have been found to be a menace to the welfare of children.

10. Authorizes emergency license control of food that might be dangerous by reason of contamination with micro-organisms. Such licensing is limited to operations in which the public health cannot be protected otherwise.

COSMETICS

11. For the first time places cosmetics under Federal supervision. Requiring cosmetics to be truthfully sold and outlaws those injurious to health.

DRUGS

12. Prohibits traffic in drugs and devices which are dangerous to health under the conditions of use prescribed in the labeling or advertising.

13. Requires habit-forming drugs to bear warning labels.

14. Requires adequate directions for use of drugs and devices and appropriate warnings against their probable misuse through overdosage, or by children, or in disease conditions where they may be dangerous.

[p. 5]

15. Sets up special protection to consumers against drugs liable to deterioration.

16. Requires that claims of effect of drugs and devices must not be false or misleading in any material particular. (The present law makes fraud, that is, wilful intent to deceive, an element of the offense; unwarranted therapeutic claims resulting from sheer ignorance of the manufacturer are not actionable.)

17. Defines "nonofficial" drugs as illegal if the standard of strength varies from the standard claimed. (The present law prescribes only those which fall below the standard claimed. Drugs which are too strong may be quite dangerous.)

18. Requires that antiseptics possess germicidal power.

19. Requires declaration on the label of the names of active ingredients of nonofficial drugs.

GENERAL

20. Prohibits the use of poisonous containers for food, drugs, and cosmetics.
21. Requires that food, drugs, and cosmetics be prepared and handled under conditions of reasonable cleanliness.
22. Forbids the use of uncertified and impure coal-tar colors in food, drugs, and cosmetics.
23. Prohibits slack-filling and the use of deceptive containers for food and drugs.
24. Provides for factory inspection and the procurement of records needed to prove Federal jurisdiction.
25. Provides increased penalties for violations.
26. Authorizes the Federal courts to enjoin violations.

[p. 6]

1.12a (2) SENATE COMMITTEE ON COMMERCE

S. REP. No. 152, 75th Cong., 1st Sess. (1937)

FOODS, DRUGS, AND COSMETICS

MARCH 8, 1937.—Ordered to be printed

Mr. COPELAND, from the Committee on Commerce, submitted, in lieu of Senate Report No. 91, the following

AMENDED REPORT

[To accompany S. 5]

The Committee on Commerce, to whom was referred the bill (S. 5) to prevent the adulteration, misbranding, and false advertisement of food, drugs, devices, and cosmetics, in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, and which was heretofore reported with certain amendments, submit herewith an amended report and recommend that the bill, as amended, do pass. The amendments are incorporated in the bill as reported.

This bill has been prepared with three basic principles in mind: First, it must not weaken the existing laws; second, it must strengthen and extend that law's protection of the consumer; and, third, it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest.

This bill meets these three principles. It has been prepared after many and extensive conferences with the enforcement agencies of the Government and with representatives of various consumer groups or associations, professional groups, and the industries to be regulated.

Separately called meetings were held with representatives of the food, drug, and cosmetic industries. Letters inviting suggestions were sent to many persons known to be interested in the subject. Several volumes of suggestions have been received from persons in the groups just mentioned. These suggestions have been carefully studied; many of them rejected; some accepted; some accepted in part or in effect. The hearings which have been held by committees of the Senate and House of Representatives on previous bills in former sessions of the Congress have been reviewed and studied to take advantage of the information and discussions contained in them. [p. 1]

ADVERTISING

1. Prohibits false advertising of food, drugs, therapeutic devices, and cosmetics.

FOODS

2. Provides for the promulgation of standards of identity and a reasonable standard of quality for food. (A standard of quality is authorized by the present law for canned food only.) In providing a standard of identity for citrus fruit, it is intended that such will be a standard of maturity only.
3. Requires the labeling of unstandardized food to disclose the ingredients by name.
4. Prohibits traffic in food which is dangerous to health. (The present law permits regulation of dangerous food only in the event that the poison is added.)
5. Prohibits addition of poison. If it cannot be avoided in production or manufacture, when it reaches the consumer the product must be safe for human use.
6. Eliminates the "distinctive name" proviso of the existing law under which the sale of products, the labels of which are misleading, are now permitted sale.
7. Requires fully informative labeling of infant and invalid food.
8. Requires label declaration of artificial colors and artificial flavors in food.
9. Forbids traffic in confectionery containing metallic trinkets and other inedible substances which have been found to be a menace to the welfare of children.

10. Authorizes emergency license control of food that might be dangerous by reason of contamination with micro-organisms. Such licensing is limited to operations in which the public health cannot be protected otherwise.

COSMETICS

11. For the first time places cosmetics under Federal supervision. Requiring cosmetics to be truthfully sold and outlaws those injurious to health.

DRUGS

12. Prohibits traffic in drugs and devices which are dangerous to health under the conditions of use prescribed in the labeling or advertising.

13. Requires habit-forming drugs to bear warning labels.

[p. 5]

14. Requires adequate directions for use of drugs and devices and appropriate warnings against their probable misuse through overdosage, or by children, or in disease conditions where they may be dangerous.

15. Sets up special protection to consumers against drugs liable to deterioration.

16. Requires that claims of effect of drugs and devices must not be false or misleading in any material particular. (The present law makes fraud—that is, willful intent to deceive—an element of the offense; unwarranted therapeutic claims resulting from sheer ignorance of the manufacturer are not actionable.)

17. Defines "nonofficial" drugs as illegal if the standard of strength varies from the standard claimed. (The present law prescribes only those which fall below the standard claimed. Drugs which are too strong may be quite dangerous.)

18. Requires that antiseptics possess germicidal power.

19. Requires declaration on the label of the names of active ingredients of nonofficial drugs.

GENERAL

20. Prohibits the use of poisonous containers for food, drugs, and cosmetics.

21. Requires that food, drugs, and cosmetics be prepared and handled under conditions of reasonable cleanliness.

22. Forbids the use of uncertified and impure coal-tar colors in food, drugs, and cosmetics.

23. Prohibits slack-filling and the use of deceptive containers for food and drugs.

24. Provides for factory inspection and the procurement of records needed to prove Federal jurisdiction.

25. Provides increased penalties for violations.

26. Authorizes the Federal courts to enjoin violations. [p. 6]

1.12a (3) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 2139, 75th Cong., 3rd Sess. (1938)

FOOD, DRUG, AND COSMETIC ACT

APRIL 14, 1938.—Committed to the Committee of the Whole House on the state of the Union and ordered to be printed

Mr. LEA, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany S. 5]

The Committee on Interstate and Foreign Commerce, to whom was referred the act (S. 5) to prevent the adulteration, misbranding, and false advertising of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, report favorably thereon with an amendment and recommend that the act do pass.

The committee amendment strikes out all of the Senate bill and inserts in lieu thereof a substitute which appears in the reported bill in italic type.

The act herewith reported is the culmination of more than 5 years of study by your committee.

GENERAL PURPOSES

This act seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906, as amended (U.S.C., title 21, secs. 1–15). That act is popularly known as the Wiley pure-food law, because that great pioneer in pure food and drug legislation, Dr. Harvey W. Wiley, led the fight for its enactment.

While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. [p. 1]

Section 701 relates generally to regulations. In the case of regulations, the violation of which constitutes an offense, it is required that appropriate notice of a public hearing be given and that adequate time shall be given after the promulgation of a regulation before it becomes effective.

PROCEDURE GOVERNING FORMULATION AND JUDICIAL REVIEW OF REGULATIONS

Section 701 (e), (f), and (g) of the committee amendment set forth the procedure governing the formulation and judicial review of certain regulations to be issued by the Secretary. These regulations include those with respect to the following matters: Establishing definitions and standards of identity, standards of quality, and standards of fill of container for foods (sec. 401); information on label concerning vitamin, mineral, and dietary properties of foods (sec. 403 (j)); limitations on quantity of added poisonous or deleterious substances whose presence cannot be avoided by good manufacturing practice (sec. 406 (a)); issuance of temporary permits governing manufacturing, processing, or packing so as to prevent contamination with micro-organisms (sec. 404 (a)); prescribing appropriate tests on methods of assay to determine [p. 9] strength, quality, or purity of drugs (sec. 501 (b)); designation of drugs as habit-forming (sec. 502 (d)); directions on label as to use of drugs (sec. 502 (f)); statements on label as to precautions necessary by reason of liability of drug to deterioration (sec. 502 (h)); and listing of harmless coal-tar colors and certification of batches thereof for food, drugs, or cosmetics (secs. 406 (b), 504, and 604).

Such regulations are not merely interpretive. They have the force and effect of law and must be observed. Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported.

Hearings.—A proposal to issue, amend, or repeal any such regulation is to be made by the Secretary of Agriculture on his own initiative, or by the interested industry or a substantial portion thereof, and the Secretary is required to set the proposal for hearing. The proposal is to be set forth in general terms so that the Secretary will be free to frame the precise language of the regulation or amendment or repeal in the light of the evidence developed at the hearing.

As a result of the hearing on the proposal the Secretary may determine to issue, amend, or repeal the regulation, or not to do so.

In either case, however, he is required to issue and make public an order specifying the action taken. This will prevent the pocketing of proposals to issue, amend, or repeal a particular regulation and eliminate application of the "negative order" doctrine which denies court relief where the executive officer merely fails to take any affirmative action.

If as a result of the hearing on any proposal the Secretary determines to issue, amend, or repeal the regulation, the action taken may be based only on substantial evidence of record at the hearing. Similarly, the action of the Secretary in failing to carry into effect any proposal for issuance, amendment, or repeal of a regulation set for hearing must rest on a like basis. In either instance detailed findings of the facts on which the action of the Secretary is based are required to be made public as a part of his order. It follows that if the order of the Secretary is to be valid, the Government must have placed in the record at the hearing its evidence in support of the action taken and thereby afford opportunity for persons affected to controvert viva voce the Government's evidence. While common law or jury trial rules of evidence need not be enforced at such hearing, nevertheless it is essential to such a hearing that all the evidence on which the administrative officer acts be disclosed at the hearing and that the right to controvert viva voce be accorded. Cf. *Ohio Bell Tel. Co.* v. *Public Utilities Comm. of Ohio* (1937) 301 U.S. (preliminary print) 292.

The order of the Secretary is to take effect not earlier than 90 days after it is issued and made public, except that if the Secretary finds that emergency conditions so require, and specifies in the order his findings as to such conditions, then the order may take effect at an earlier date.

Judicial review.—Judicial review of the order of the Secretary with respect to any proposal for the issuance, amendment, or repeal of a regulation may be had in a district court of the United States.

Such review may be had on the initiative of any individual or business organization by instituting the special review proceedings [p. 10] provided in the committee amendment within 90 days after issuance of the Secretary's order. The complainant can institute the proceedings only in a case of actual controversy as to the validity of the order, thereby meeting the constitutional requirement for vesting in the Federal courts jurisdiction only of "cases" or "controversies."

Such review proceeding is to be instituted by filing a complaint in the district court for the district where the complainant resides or has his principal place of business. The new Rules of Civil Procedure for the District Courts of the United States which will take effect following the present session of Congress, will govern the form of complaint, service of summons, and the like. There is one exception. Personal service on the Secretary may be had anywhere in the United States even though he is without the territorial limits of the State in which the court is held.

In such special review proceeding the court will have jurisdiction to enjoin the Secretary from enforcing the order if it is invalid and may also compel him to issue an order providing for such regulation, amendment, or repeal as will be in accordance with law if justice requires that such affirmative action be taken.

Further opportunity for review of a regulation placed in effect by the Secretary will occur in criminal, injunction, libel for condemnation, exclusion of imports, or other proceedings instituted by the Government under the bill, in which the defendant is charged with violating the regulation (see secs. 302, 303, 304, and 801). If, through prior review proceedings, there has been a final determination of the validity of the regulation or order in question by the Supreme Court of the United States, or the circuit court of appeals for the particular circuit, then the question of validity would likely have become stare decisis. If, however, this is not the case, the validity of the regulation or order could be inquired into and determined in such criminal, injunction, libel for condemnation, exclusion of imports, or other proceeding.

There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.

The special type of review above outlined, where the proceedings are instituted by the individual or business organization affected, will permit an early determination of the validity of the Secretary's action with respect to any proposal for a regulation, amendment, or repeal, and make for prompt certainty as to legal rights.

In each of the types of review proceeding above outlined the transcript of the record and proceedings before the Secretary on the proposal resulting in the order, may become a part of the evidence in the court. In the special review proceedings the Secretary is required to certify and file the transcript in the court. In the other cases, a certified copy of the transcript is required to be furnished by the Secretary and is admissible in court. The special review provisions also specifically provide that the court is to permit the private individual or concern to supplement the evidence in such transcript by adducing additional evidence (which the Secretary may rebut) bearing on the validity of the order, but only on a showing that such additional evidence is material and that there were reasonable grounds for failure to adduce it before the Secre- [p. 11] tary. While this right to adduce additional evidence inheres in the criminal and libel proceedings originating in court, specific provision is made for it in the committee amendment in connection with the special review proceedings. The additional evidence could be taken before the court or a master, or, in the case of the special review proceeding, the court may remand the case to the Secretary for the taking of such evidence if the court deemed that desirable because of the amount of such evidence or its technical character, or in order to permit the Secretary to amend his order in the light of such additional evidence, or for any other reason.

The committee amendment is silent as to any limitations on the court in holding invalid the order of the Secretary. The court is thus left free to exercise its right of review to the full extent that it may constitutionally do so. A regulation would, of course, be invalid if the Secretary failed to observe the procedural requirements as to hearing, notice, and the like, or if the order, as specifically required by the committee amendment, was not based on substantial evidence of record at his hearing, or went beyond or was contrary to the Secretary's own finding, or to constitutional or jurisdictional limitations. Furthermore, the order would be invalid if for any other reason it was not in accordance with law. The court can take into consideration the additional evidence, if any, adduced before it, and to the extent that it may constitutionally do so, weigh the combined evidence, and hold the order invalid if in the light of such evidence it appears that the findings on which the Secretary based the order are not true in fact or that the order is unreasonable, arbitrary, or capricious. [p. 12]

PART 2

FOOD, DRUG, AND COSMETIC ACT

APRIL 21, 1938.—Ordered to be printed

Mr. CHAPMAN, from the Committee on Interstate and Foreign Commerce, submitted the following

MINORITY VIEWS

[To accompany S. 5]

The undersigned, members of the Committee on Interstate and Foreign Commerce, submit the following minority views with respect to one of the most important features of the bill, namely, provisions for court review of regulations of section 701 (f).

It is our view that the bill, if enacted with this review provision, will not afford any substantial improvement in consumer protection over the terms of the present law. In fact, in some respects it represents an impairment of the consumer-protective features of the present law.

Section 701 (f) sets up a method of court review of regulations that is wholly unprecedented. It is specifically provided that this method of review is in addition to, and not in substitution for, other methods of review provided by law, such as equity proceedings and proceedings under the Declaratory Judgment Act.

Regulations subject to this new form of review relate to the identity and quality of food; to requirements for informative labeling of special dietary food, such as that used by infants and invalids; to food contaminated with disease organisms where distribution might result in serious epidemics; to the addition of poisons to food; to the certification of coal-tar colors for use in foods, drugs, and cosmetics; to establishing adequate laboratory tests for important official drugs; to the listing of narcotic and habit-forming drugs; to label warnings against probable misuse of dangerously potent drugs; and to label directions for the preservation of potent drugs liable to deterioration.

These provisions constitute the very heart of any worthy food and drug legislation. If the public health and welfare are to be adequately safeguarded, regulations putting these provisions into effect should be promptly and effectively enforceable and certainly should be subject to no greater restrictions and delays in review by the courts to determine their validity than regulations authorized by other Federal laws which deal with economic questions [p. 1] rather than the vital questions of public health concerned in this legislation.

Section 701 (f) permits any person who will be adversely affected by one of the regulations listed above to file, any time within 90 days after the regulation has issued, a complaint in the district court for the district where such person resides or has his principal place of business to enjoin the Secretary of Agriculture from enforcing the regulation. For example, if a regulation is issued requiring label warnings against probable and dangerous misuse of a certain class of patent medicine, then each manufacturer of that class of medicines and each dealer who profits by the sale of the medicines may file a complaint in his local district court to enjoin the enforcement of the regulation. If a single district judge could be found who would issue an injunction against such enforcement, the regulation could not be enforced at any place in the United States, even though every other district judge in the country had refused to issue an injunction. The provision would therefore clothe each and every district judge with authority to block the enforcement of a regulation throughout the United States. This is an extraordinary extension of jurisdiction and an extraordinary grant of power never heretofore seriously advanced in the entire history of the country. As suggested in the letter of the Secretary of Agriculture, a copy of which is hereto attached, if there is to be an exploration into new forms of court review of administrative regulations specifically authorized by congressional enactment, it is our conviction that such experimentation should be made in fields other than those of vitally important health laws.

Even if the injunction which blocks the enforcement of a regulation can be overturned in appellate courts, there is a provision under the preceding subsection (701 (e)) whereby the question can be reopened and the regulation again subjected to the same hazards. This provision requires that—

> the Secretary, on his own initiative, or at the request of any interested industry or substantial portion thereof, *shall* hold a public hearing upon a proposal to issue, amend, or repeal any regulation * * * [Italics supplied.]

If the manufacturers of the class of patent medicines referred to above, or any substantial proportion of such manufacturers, demanded a public hearing on a proposal to amend or repeal a regulation previously validated by the courts after litigation under subsection (f), the Secretary would have no alternative but to hold such a hearing and to follow the prescribed procedure laid down by subsection (e) under which he would issue an order containing the regulation in effect. The continuation of the regulation by such order would then become subject within the 90-day period prescribed, to the filing of a second crop of complaints throughout the United States. If a single district judge could again be found to issue an injunction, the regulation would again be rendered ineffective.

In most of the industries affected by the bill there are sufficient minorities, vociferously opposed to any form of regulation, to form a substantial proportion of the industry. These could be depended upon in practically every instance in which a regulation is required for the protection of public welfare to resort to the tactics above described and prevent indefinitely the effectuation of the purpose of the law. [p. 2]

The procedure set up in the bill to restrain the Secretary, while in form only seeming to protect industry rights, in effect amounts to the placing of the control of enforcement in the hands of those whose interests are contrary to public welfare and who have created the need for legislation.

It is true that the scope of the old law is broadened by the bill to include cosmetics, therapeutic devices, and certain drugs which are not now subject to regulation. It is true that in many instances the definitions of adulteration and misbranding have been expanded and strengthened, although even these improvements are studded with a notable number of exceptions. It is also true that the procedural provisions have been strengthened through authorization of injunction proceedings, although this, to some extent, is nullified by changes from the seizure section of the existing law, particularly that under which trial of seizure cases will in many instances occur in producing jurisdictions before juries whose sympathies would ordinarily be with local industries rather than in consuming jurisdictions where juries would be expected to display less bias.

Weighing the advantages and disadvantages for the protection of consumer welfare presented by the terms of this bill, we are unable to escape the conclusion that because of the extraordinary provision for court review of regulations in section 701 (f), which would postpone indefinitely the consumer protection that can now be afforded in some degree by the present law in much of the field to be covered by these regulations, it would be better to continue the old law in effect than to enact S.5 with this provision.

If there is to be exploration into new methods of court review, such a radical departure from the well-established Federal procedure as is here proposed should be the subject of a separate bill, applicable to all Federal laws authorizing regulations, to be considered on its own merits. This important health legislation should not be made the sole medium for such experimentation.

Under date of March 28, 1938, the undersigned [Chapman and Mapes] submitted the then latest draft of section 701, the court-review section, of the bill to the Secretary of Agriculture and asked for his views in regard to the same.

The following is a copy of his reply:

MARCH 29, 1938.

HON. CARL E. MAPES,
House of Representatives.

MY DEAR MR. MAPES: Receipt is acknowledged of your letter of March 28, 1938, with which you enclose a copy of chapter VII, General Administrative Provisions, section 701, from the latest edition of S. 5 as agreed upon by the Interstate and Foreign Commerce Committee of the House. You ask for an expression of my opinion of the effect of the provisions of this section upon the administration of the measure.

I am of the opinion that if section 701 (f) remains in the bill its effect will be to hamstring its administration so as to amount to a practical nullification of the substantial provisions of the bill.

The clear intent of S. 5 is to close the channels of interstate commerce to food, drugs, devices, and cosmetics that are adulterated or misbranded. Because of the complex and technical nature of the subject matter involved a number of the most important definitions of adulteration and misbranding are incomplete and must have their clearly stated outlines filled in with scientifically accurate details before they can be enforced. The bill delegates to the Secretary of Agriculture the quasi-legislative power to ascertain the necessary technical facts and supply the details that will complete these definitions, thus effectuating the legislative will. [p. 3]

The Secretary is entrusted with these powers in connection with sections 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (f) exclusive of the proviso, 502 (h), 504, and 604. These sections are extremely important. They relate to the identity and quality of food, to requirements with respect to special dietary food, to contaminated food, to poisonous substances in food, to coal-tar colors in food, drugs, and cosmetics, to determining adequate tests for official drugs, to narcotics and habit-forming drugs, to probable misuse of dangerously potent drugs, and to labeling drugs liable to deterioration.

Section 701 (f) permits any person who will be adversely affected by any order authorized by the sections listed above to file, any time within 90 days after the issuance of the order, a complaint in the district court for the district where such person resides or has his principal place of business, to enjoin the Secretary from placing the order in effect. This subsection contains the unique provision directing the courts to permit the complainant to supplement the evidence recorded in the Secretary's hearing upon which the order was based. This constitutes an invitation to those who would obstruct the enforcement of a regulation to withhold or conceal evidence that should have been given in the hearing and to employ such evidence merely for the purpose of upsetting the order and thus postponing indefinitely the enforcement of the regulation. In the event such order is upset there is nothing to prevent the same complainant from instituting new proceedings on a new order and thereby causing further delay. In fact, every amendment of an order could be a ground for the institution of new proceedings.

Even though a number of district courts might uphold an order, demanded alike by the public and by the overwhelming majority of the industry regulated, to terminate abusive practices, a single district court could enjoin permanently the enforcement of the regulation.

Frankly, I regard this provision as unfair to the Department, to the public, and to the industries regulated, the majority of which unquestionably would support regulations, based on substantial evidence, which the Secretary of Agriculture would promulgate. It would constitute a serious impediment to orderly administrative operations. If a bill containing this provision were enacted it would not constitute any material contribution to the public protection that the Department cannot now extend under the existing law. In some respects it would afford even less protection than that afforded by the existing law, which is broad and general in its terms and is to some degree applicable and effective in the fields covered by the sections involved in this discussion.

It is the Department's considered judgment that it would be better to continue the old law in effect than to enact S. 5 with this provision.

If there is to be exploration into new fields of administration law, may I urge that it not be in the field of vitally important public health legislation.

There has not been sufficient time to permit the Department to ascertain the relation of the foregoing to the program of the President.

Sincerely yours,

H. A. WALLACE, *Secretary*.

Attention is called especially to the following statements in the letter of the Secretary:

> I am of the opinion that if section 701 (f) remains in the bill its effect would be to hamstring its administration so as to amount to a practical nullification of the substantial provisions of the bill.
>
> It is the Department's considered judgment that it would be better to continue the old law in effect than to enact S. 5 with this provision.
>
> If there is to be exploration into new fields of administrative law, may I urge that it not be in the field of vitally important public health legislation.

The section as submitted to the Secretary of Agriculture was the same as the section as reported by the majority of the committee, except in two particulars, one of which weakens the enforcement provision of the section, the other of which has no effect on it one way or the other, in our opinion.

The committee amended the draft of the section as submitted to the Secretary, (1) by striking out of the committee substitute, page 82, line 19, after the word "shall", the words "if in his judgment sufficient reason appears for so doing"; and (2) by inserting, page 84, line 8, after the word "shall", the words "upon the show- [p. 4] ing that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence at the proceeding before the Secretary."

As stated, the first amendment weakens the enforcement provision of the section. The second one requires nothing more than a court would ordinarily require without it.

If this bill is enacted into law with section 701 (f), the court-review section, in it, as reported by a majority of the committee, what started out as an effort on the part of the advocates of a more adequate food and drug law to enlarge the scope of the existing law, to fill in the loopholes in it, and to put more teeth into it, will end with having accomplished the directly opposite result and years of earnest effort will have gone for worse than naught.

VIRGIL CHAPMAN,
JERRY J. O'CONNELL,
CARL E. MAPES,
CHAS. A. WOLVERTON,
JAMES WOLFENDEN,
PEHR G. HOLMES. [p. 5]

1.12a (4) COMMITTEE OF CONFERENCE

H.R. REP. No. 2716, 75th Cong., 3rd Sess. (1938)

FOOD, DRUG, AND COSMETIC ACT

JUNE 11, 1938.—Ordered to be printed

Mr. LEA, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 5]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 5) to prevent the adulteration, misbranding, and false advertisement of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

Chapter I—Short Title

Section 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

Chapter II—Definitions

* * * * * * *

[p. 1]

Chapter VII—General Administrative Provisions

Regulations and Hearings

Sec. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Agriculture shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of [p. 16] *the United States and regulations promulgated thereunder.*

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504 and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in

the court the transcript of the proceedings and the record on which the Secretary based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

[p. 17]

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

[p. 18]

1.12a (5) CONGRESSIONAL RECORD

1.12a (5) (a) VOL. 81 (1937), March 9: Amended and passed Senate, p. 2019

[No Relevant Discussion on Pertinent Section]

1.12a (5) (b) VOL. 83 (1938), June 1: Amended and passed House, pp. 7891–7899

Mr. MAPES. Mr. Chairman, I offer an amendment, which I send to the Clerk's desk.

The Clerk read as follows:

Amendment offered by Mr. MAPES: Page 83, line 20, strike out all of paragraph (f), section 701, and insert the following:

"(f) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may obtain a review of such order in the circuit court of appeals of the United States within any circuit where such person resides or carries on business by filing in the court, within 60 days from the date of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, and thereupon the Secretary shall certify and file in the court a transcript of the entire record in the proceeding, including all the evidence taken and the report and order of the Secretary. Upon such filing of the petition and transcript the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have power to make and enter upon the pleadings, evidence, and proceedings set forth in such transcript a decree affirming, modifying, or setting aside the order of the Secretary. The findings of the Secretary as to the facts, if supported by evidence, shall be conclusive. If either party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceedings before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearings in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings. which, if supported by evidence, shall be conclusive, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 240 of the Judicial Code."

Mr. MAPES. Mr. Chairman, I ask unanimous consent to proceed for 5 additional minutes.

The CHAIRMAN. Is there objection to the request of the gentleman from Michigan?

There was no objection.

Mr. MAPES. Mr. Chairman, it is unfortunate to have to consider an amendment of this importance with so few Members on the floor. Several months ago the Committee on Interstate and Foreign Commerce, which reported the pending committee substitute, [p. 7891] brought in a bill to amend the Federal Trade Commission Act. The amendment which I have offered is the same as the court review section in the Federal Trade Commission Act with only such changes as are necessary to adapt it to the pending bill. In substance my amendment is identical with the provision reported by the Committee on Interstate and Foreign Commerce relating to the Federal Trade Commission, except that it applies to the Food and Drug Administration instead of the Federal Trade Commission. I referred yesterday to similar provisions in the acts relating to other regulatory bodies. At that time I did not have before me this act relating to the Federal Trade Commission. As I said yesterday, nowhere is there any law that I know of having to do with a regulatory body that is comparable or similar to the provision contained in the pending bill. This legislation started out to enlarge the scope of the food and drug law and the jurisdiction of the Food and Drug Administration, but if this section remains in the bill it will end up by materially weakening and limiting the authority of the Food and Drug Administration.

The chairman of the Committee on Interstate and Foreign Commerce yesterday stated that the minority report was unfair and unwarranted, in that it quoted a letter of the Secretary of Agriculture with reference to this legislation. When did it become unfair or unwarranted to let the membership of the House know what the views of the head of a great department are in regard to legislation affecting one of the principal bureaus of his department? I find myself in the position of trying to sustain, as against the majority of the committee, the views of not only the Department of Agriculture, but the Department of Justice as well, with reference to this legislation.

I hold in my hand a memorandum which was prepared by the Department of Justice with reference to this bill. I may say it was not prepared for me or at my request. However, I have been authorized over the telephone to say that it was prepared in the Department of Justice and expresses the views of that Department in regard to some of the provisions of this bill.

I shall read extracts from it and put the rest of it in the RECORD without taking the time to read it. It is as follows:

> RE S. 5—PURE FOOD AND DRUG BILL
>
> Section 701 (f), which relates to judicial review of the orders of the Secretary of Agriculture by means of injunction suits in the United States district courts, constitutes a radical and undesirable departure from established practice.
>
> This section provides that any person adversely affected by any such order may bring an injunction suit against the Secretary of Agriculture in the district wherein such person resides or has his principal place of business. The consequence of such grant of jurisdiction would be to subject the Secretary to the possibility of injunction suits by different parties in 85 different districts to review the validity of the same order. The Secretary conceivably might be required to defend simultaneously numerous suits in as many as 85 jurisdictions.

Now, listen to this:

> Not only would this result in an intolerable burden on the Government, in that Government attorneys, Department of Agriculture experts, Government files, laboratory specimens, etc., would have to be carried from district to district, but divergence of decisions might result which would tie up enforcement for months and even years until the conflict of decisions is ironed out by a series of decisions of the circuit courts of appeals or by a decision of the Supreme Court of the United States. The ultimate result would be to seriously hamper and weaken the enforcement of the Pure Food and Drug Act.
>
> Under existing law, heads of Government Departments are suable only in the District of Columbia, because the District of Columbia is regarded as their official residence.

Do the members get that? Under existing law, heads of Government Departments are suable only in the District of Columbia.

> No reason appears for extending preferential treatment in that respect to litigants under the Pure Food and Drug Act, which is not extended to litigants against heads of other Government Departments or to litigants who sue the Secretary of Agriculture under other statutes.

That is not my language. It is the language of the Department of Justice.

The memorandum continues:

> If the long-standing and established practice is followed, persons who feel aggrieved at an order of the Secretary of Agriculture, and desire a judicial review of the validity of his action, should be required to pursue their remedy in the District Court of the United States for the District of Columbia. In that way not only would the Government be saved the intolerable burden above mentioned but a diversity of decisions would be prevented, and a final determination could be expeditiously secured in a single jurisdiction as to the validity of an order of the Secretary. In this way the citizen would have his day in court and would be accorded the full and complete right of judicial review of the validity of an administrative order or regulation. At the same time interference with enforcement of administrative orders and regulations, and the orderly conduct of governmental business would be reduced to a minimum.
>
> It is, therefore, suggested that if this subsection is to remain in the bill, it should be amended by striking the words "for the district wherein such person resides or has his principal place of business" from page 83, line 25, to page 84, line 1, of the bill, and substituting in lieu thereof "for the District of Columbia."

And now listen to this, and this again is the language of the legal Department of the Government, the Department of Justice. I tried to make this clear yesterday, and I am glad to be substantiated by the Department of Justice.

> As a matter of fact, the entire subsection is really unnecessary, because even without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court.

The memorandum then discusses another section of the bill. While that part of the memorandum is not pertinent to my amendment, I will incorporate it in the RECORD. It is as follows:

> Sections 304 (a) and (b) which relate to seizure, contain provisions under which the owner of the article libeled by the Department of Agriculture may secure under certain circumstances a change of venue at his option. No such privilege, however, is accorded the Government. Why a defendant should be extended the option of choosing in what jurisdiction he should be sued, and yet the Government should be precluded from making a selection of the district in which suit should be brought, appears to be inexplicable.
>
> It should be noted that under the Federal judicial system, changes of venue are unknown. There are no provisions in Federal statutes permitting either party to move for a change of venue. No reason appears for introducing this remedy in respect to one type of proceedings under a special statute. Moreover, if the remedy is to be accorded at all, it should be equally available to both parties.
>
> Specifically, sections 304 (a) and (b) provide that if two libels are pending involving the same person and the same issues, in two or more districts, the claimant may require that the proceedings be consolidated for trial and tried in any one of such districts which is selected by him. Why should not the selection be made by the Government, which is the plaintiff in the libel proceedings?
>
> The section further provides that the trial in such cases may also be had in a district in a State contiguous to the State of the claimant's principal place of business, such district to be agreed upon by stipulation or to be designated by the court. In other words, under the second alternative, the claimant in a series of libel proceedings may insist on having all the libels transferred to one district, and at that a district in which none of them is pending, so long as such district is contiguous to the State of the claimant's principal place of business. No reason appears for according to the owner of articles charged with being in violation of the Pure Food and Drugs Act, the right to select the forum in which the issues shall be determined.
>
> It is suggested, therefore, that section 304 (a) be amended by entirely striking therefrom the clause beginning with the word "and" on line 14, page 53, and ending with the end of the subsection; and that section 304 (b) be amended by entirely striking therefrom lines 4-21, inclusive, on page 54 of the bill.

Then the Department of Justice concludes:

> It is important to observe that the provisions to which objection is made are not limited to the new powers proposed to be granted to the pending bill.

It would seem as if the writer of the minority report, which the chairman of the committee says is unwarranted and unfair, might have had some consultation with the Department of Justice before drafting the report. Let me assure you, however, that he did not have any such consultation.

The Department of Justice says, I repeat—

> It is important to observe that the provisions to which objection is made are not limited to the new powers proposed to be granted by the pending bill. They would affect the enforcement of the present law, as well as of the new law, and therefore, are particularly undesirable in that they may undermine, hamper, and weaken the entire enforcement of the Pure Food and Drugs Act.

[p. 7892]

The Secretary of Agriculture states the enactment of this section would hamstring the Department in the enforcement of the Food and Drugs Act.

The Department of Justice memorandum closes with this statement:

> While undoubtedly this is not the intention, unfortunately, it may be the result of the enactment of the bill in its present form.

Why should the Food and Drug Administration, among all the regulatory bodies of the Government, be singled out for special treatment and, in the language of the Secretary of Agriculture, be hamstrung in its enforcement of food and drugs laws providing for the protection of the health and the well-being of the consuming public—the men, women, and children of the

United States? Why should the Food and Drug Administration be put on trial? Why one rule for other regulatory bodies and another for the Food and Drug Administration?

Perhaps the apple growers have been overemphasized in this debate. They are not the only ones affected by this law. The law applies to proprietary patent medicines, to impure and adulterated foods and drugs of all kinds, and to cosmetics and devices. Is the House ready to weaken the administrative efficiency of the Food and Drug Administration in all its regulatory work merely to satisfy the complaints of the apple growers? If this bill applied only to apple growers perhaps this section would not be so objectionable, but it applies to all violators of the food and drugs law or to all who come within its provisions. As the Secretary of Agriculture states in his letter which is printed in the minority report, the enactment of this section as it stands will hamstring the Food and Drug Administration in the enforcement of the entire law.

* * * * *

Mr. ROBERTSON. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, I do not intend to enter into any elaborate discussion of this amendment. The effect of the amendment is simple. It makes a departmental order supreme and denies to those affected a day in court. It makes it virtually impossible for any user of a spray material for fruit or vegetables to test in court the reasonableness of a departmental order affecting residue tolerance.

The amendment seeks to accomplish this in two ways. In the first place, it provides that if there be any evidence whatever, regardless of how inconsequential or flimsy it may be, to support the findings of the Department of Agriculture, such evidence becomes conclusive and binding upon the court. You do not have any hearing on the facts under this amendment. Of course, the Department would have some evidence, but our position is that it should be evidence that is substantial and that, in the opinion of a reasonable court, would justify the court in upholding the order of the Department that issued it.

The second provision of this amendment—and I could not follow my friend fully on this, but I understood him to say yesterday he wanted to bring all these cases to the District of Columbia. I now understand that some cases could be heard in the circuit court of appeals of the State in which they arose, but if the question at issue is Nation-wide in its effect, it still has to come to the District of Columbia.

Mr. MAPES. Mr. Chairman, will the gentleman yield?

Mr. ROBERTSON. I yield.

Mr. MAPES. As I said in answer to an interruption, I have gone more than half way to meet the views of the Committee on Interstate and Foreign Commerce as expressed in the recent bill which the committee reported relating to the Federal Trade Commission.

Mr. ROBERTSON. Mr. Chairman, this court-review section has been provided in the Senate bill, and I feel that I am justified in stating to the House that this bill will be enacted into law by the Senate without it. This court-review section is approved by a majority of the committee that brings this bill to us. It has the support of every apple organization in the United States. It has the support of all the organizations representing the production of any type of fruit or vegetable where spray must be used in the production.

If we adopt this amendment we will leave thousands and thousands of farmers in this Nation who must depend upon the reasonableness of departmental regulations with respect to spray residue to keep their products on the market at the mercy of the Department. We have had an illustration within the past five years of what might happen to them. Dr. Tugwell, Acting Secretary in the absence of the Secretary of Agriculture, in misguided enthusiasm to protect the public health, well meaning but ignorant of what was involved, promulgated a tolerance as to lead residue that was nearly 100 percent below the then existing tolerance. It would have put every apple producer in the United States out of business. It was so capricious and so unreasonable that as soon as the Secretary got back and considered the matter he reversed it and restored the previous tolerance. That happened once. It could happen again; and under the amendment proposed by our distinguished colleague from Michigan fruit and vegetable raisers could be destroyed without a day in court. I do not believe for a minute this House will vote to subject the farmers of this Nation to any such hazard at a time when we all know they are not making both ends meet. [Applause.]

[Here the gavel fell.]

[p. 7893]

Mr. MAPES. Mr. Chairman, it provides in the first place that anyone who desires to test the validity of a regulation or order of the Food and Drug Administration, instead of being permitted to go into any district court of the United States, must go before a circuit court of appeals within the district in which he resides. The hearing would then come up before a three-judge court instead of a one-judge court. The action would be confined to 10 circuits instead of to 85 districts. The amendment also contains the usual provision, that the court is bound by the findings of fact of the Food and Drug Administration if supported by substantial evidence, or evidence, and if new evidence is discovered after the hearing, then the court, instead of opening the case and taking the testimony itself, must remand the case to the Food and Drug Administration to take the additional evidence. That is the usual provision.

Mr. VOORHIS. What about injunctions under the gentleman's amendment?

Mr. MAPES. The injunction matter is outside of both of these provisions. The injunction remedy by any aggrieved person is had without reference to the provisions in the bill or to my amendment.

Mr. VOORHIS. I thank the gentleman.

Mr. COFFEE of Washington. Mr. Chairman, will the gentleman yield?

Mr. VOORHIS. Yes.

Mr. COFFEE of Washington. Section 701 (f) which is involved in this dispute at the present time is the one to which the leading women's clubs and consumers' organizations in America are offering objection, is it not?

Mr. VOORHIS. So I understand.

Mr. COFFEE of Washington. Every organization of which I know anything that has made a study of this question is bitterly opposed to section 701 (f).

Mr. THOMAS of Texas. Mr. Chairman, will the gentleman yield?

Mr. VOORHIS. Yes.

Mr. THOMAS of Texas. To ask a question of our colleague from Michigan [Mr. MAPES]. Under section 701 (f) of the bill, suppose a manufacturer is making improperly some type of food or drug, and persisted in that distribution. How long would it take under that procedure before the Government could really stop him from using the channels of interstate commerce?

Mr. MAPES. I do not know that I can answer that question.

Mr. VOORHIS. We have had some experience, I believe, with other types of legislation.

Mr. LEA. Mr. Chairman, will the gentleman yield?

Mr. VOORHIS. Certainly, I yield to the chairman of the committee.

Mr. LEA. Under this bill the Government can act in that case within 24 hours.

Mr. THOMAS of Texas. The Government can act within 24 hours, but how effectively can it act within a year even?

Mr. LEA. It can stop the circulation of it in 24 hours, because under this bill we give the Food and Drug Administration the right to an injunction to stop it immediately.

Mr. THOMAS of Texas. And that injunction remains in effect until it goes through the regular routine of court procedure?

Mr. LEA. We give that power to the Food and Drug Administration in every case, practically, that is involved here.

Mr. THOMAS of Texas. And it stops right there?

Mr. LEA. Yes, absolutely; and that is a new power we give, by the way.

Mr. VOORHIS. Mr. Chairman, as I understand the provisions of section 701 (f) it would mean that if one district court was willing to issue an injunction holding up an order of the Secretary under this bill, that that would mean that that order could not go into effect regardless of how serious or important the provision was, and because it avoids that possibility, it seems to me, that the amendment of the gentleman from Michigan is a worthy one, and should be supported. I believe we have had experience with other types of legislation, where we have seen an endless amount of litigation take place, where we have seen the machinery hung up over long periods if time. This is a matter where we are attempting to get effective regulation for the protection of the health of the people, and I would hope, as was said by the gentleman from Michigan, that we would not have to hamstring the Administration in that fashion. I call the attention of the House also to the fact that no such provision as this is in existing law, that this is a new departure and that it further complicates the situation over what we have now, and that if we wish to strengthen the Food and Drug Administration, we should not take the step of writing section 701 (f) in the bill.

The CHAIRMAN. The time of the gentleman from California has expired.

* * * * *

Mr. ROBERTSON. Because he does not get a hearing in the courts on the facts but only on the law; yet the Government in its prosecution of those cases where residue tolerances have been exceeded have never thus far proven a case where spray residue has been injurious to the human body.

Mr. SAUTHOFF. That is not the question. The question here involved is the remedy, and the remedy exists if I am not mistaken. You have your hearings before the Secretary, your facts are produced before the Secretary; and the law, of course, must conform to the facts. That is your case. Any grower who feels himself aggrieved, of course, has the right to get an injunction. It seems to me as I look over this amendment offered by the gentleman from Michigan that it is an excellent amendment and much better than section 701. Section 701 seems to me to hamstring our law and make it pretty easy for the makers of proprietary and patent medicines to defeat the wishes of Congress by constantly going into various hearings and taking appeals from the hearings and going into court for injunctions. With 85 different district courts, just think of the chance a chain store has. It could undoubtedly prolong litigation and hold it up in one State after another. The way to avoid that, in my judgment, is to hold the hearing before the Secretary, and let the Secretary make his findings. If, then, the applicant feels himself aggrieved, let him take an appeal to the circuit court of appeals rather than to the district court, because there are a limited number of circuit courts of appeal; and, secondly, when a decision is handed down you are more apt to have uniformity of decisions. This stands to reason. In looking over the amendment offered by the gentleman from Michigan it seems to me ample remedy is afforded to any applicant who feels himself aggrieved, because one part of the amendment gives him the opportunity to bring any additional evidence he may have on which to make a showing.

[Here the gavel fell.]

Mr. LEAVY. Mr. Chairman, I rise in opposition to the pro forma amendment. [p. 7895]

Mr. Chairman, it is to be regretted that so many of us who apparently think alike are so far apart upon this particular amendment. The difficulty doubtless lies in the fact that the Pure Food and Drug Administration is being given power to regulate by a bureaucratic order both processed products and those that are produced naturally. The argument made in opposition to the present language in the law has some substantial weight when applied to processed products, but when you get over into the field of natural products, like all fruits and vegetables growing above ground, that have to be protected from pests by the use of spray material, then you have examples in which it does an injury that is irreparable. The individual producer can get no relief if he is denied a hearing before the order is made, and also denied a day in court as would happen if this amendment prevails.

I take issue with the gentlemen who say you can go into any Federal court and there get an injunction against an agent of the United States Government, for official actions. Every lawyer knows that the United States Government cannot be made a party defendant. No individual can bring a suit against the Government except by congressional authorization. I challenge the gentleman from Michigan [Mr. MAPES] to cite authority authorizing such general actions, as he refers to in his remarks, where the citizen can institute suit against the United States.

Mr. SAUTHOFF. Mr. Chairman, will the gentleman yield?

Mr. LEAVY. I will yield to the gentleman if he will cite me the Federal statute that authorizes an action of that kind on the part of an individual against the United States Government.

Mr. SAUTHOFF. I am not citing—

Mr. LEAVY. If the gentleman cannot give me a citation, I do not care to have more of my time consumed.

Mr. SAUTHOFF. The suit is brought against the person holding office, not against the Government.

Mr. LEAVY. The person making the order is an executive officer of the Government.

Mr. SAUTHOFF. Certainly.

Mr. LEAVY. He is appointed by the Secretary of Agriculture. The Secretary of Agriculture is appointed by the President, who is the head of the executive branch of the Government; and any court action must be against him as an official, and not as an individual; therefore it becomes a suit against the United States.

The reason this has no comparison with the citations of law concerning the Federal Trade Commission and the Communications Commission and all those other commissions is the fact that they are not executive arms of the Government; they are quasi-judicial bodies that hold hearings and determine in a judicial manner the facts. In the instant case, however, you have an executive officer who arbitrarily sits down, without hearing a particle of evidence, if he sees fit, and makes an order. That is exactly what occurred, so far as I have been able to learn, in connection with spray residue. I am sure no one will contend there was a hearing where evidence was taken, where interested parties could appear, and where a record was made.

* * * * *

Mr. ROBERTSON. Does not the gentleman from Washington think that a man who has all of his life savings invested in an apple orchard should have a day in court before we put him out of business through some departmental order?

Mr. LEAVY. I certainly do, and that is exactly what this bill gives to him. It is a question whether you are going to permit the American citizen, whose economic existence is being threatened and taken from him, the opportunity to go into court.

[p. 7895]

Mr. REES of Kansas. The assumption is that the Department of Agriculture is going to pick up the apple growers and be particularly unfair to that particular group.

Mr. ROBERTSON. No; I do not say that; but I say before you pass a law that would enable the Department to wipe out an industry you should give that industry an opportunity to have a day in court on the reasonableness of the regulations that are promulgated.

[p. 7896]

Mr. WHITE of Idaho. Is it not a fact that the apple producers and apple shippers comply with the rules and regulations of the Department of Agriculture and wash apples and prepare them for shipment in compliance with the regulations for the removal of the spray?

Mr. O'CONNELL of Montana. The very reason you are pleading here or the very reason that the apple growers are pleading here is because they do not want to comply with the regulations of the Department. They want to have this so-called spurious court proceeding or court review, which would permit them to go into courts all over the country and permit them to tie up the proceedings indefinitely, and then after a decision is rendered they will take up some other protective feature of the law and go into the courts on that, so that, finally, you will have no food and drug law whatsoever.

[Here the gavel fell.]

Mr. BUCK.

* * * * *

The only safety the average citizen, not merely the apple and pear grower, has is to require the Government to prove in every case the soundness of its regulations and the basis on which they rest. There is no way in the world, unless you leave this section in the bill, whereby not merely the apple grower, but the pear grower, or any other producer of perishable commodities can protect himself against such erratic meanderings of the minds of the departmental authorities as I have briefly cited you.

Mr. LEA. Mr. Chairman, it is unfortunate that a question of law and of legitimate procedure for the protection of the the people of the United States must be discussed with so much exaggeration and distortion as has been presented here today.

Some time ago I attended a meeting of about 300 lawyers in the city of Washington who were concerned with administrative law. It seemed to be the unanimous opinion of these men, even the men in the Government Departments themselves, that we badly need a provision regulating the court review of administrative proceedings. I believe there is no good lawyer in the United States who will not admit we are seriously in need of legislative improvement of procedure as to administrative law and practice. Our committee recognizes this, and we have attempted in this bill to provide a legitimate, orderly method of hearing these cases and disposing of them more promptly and in a way that will greatly reduce litigation. If more farsighted and progressive, the Departments would welcome provisions such as we have in this bill. With greater prestige to themselves they would face less litigation and dispose of their cases more promptly. But to the static mind every innovation, no matter how beneficial ultimately, is destructive of their rights. They cannot conceive of their being deprived of any arbitrary power to the advantage of the public.

A substitute amendment is proposed

here that seeks to gut this court-review section. It does all it can to destroy a legitimate court review without providing one that is of any use. It provides, among other things, that if the record contains any evidence to support the findings, then the court must deny relief against arbitrary action by the administrative agency. The proposal is absurd on the face of it. Nothing could be better written into the law to shield irresponsible government, than the court review in the gentleman's amendment. It is a perfect arrangement for arbitrary exercise of power without legitimate opportunity for the citizen affected to protect himself.

Mr. LEA. But the Federal Trade Commission is a semi-judicial body. Here we have a purely administrative body with no judicial procedure. Even if I supported a less desirable provision yesterday that is no reason I should repeat the mistake today.

I know of a case in one of the Departments in which three men had the right to write regulations. They were inexperienced men; they were incompetent men. They would go into a back room and write regulations, with the result that there was a regular stream of irresponsible regulations coming from that Department. After a little experience was applied to their regulations they appeared as utterly ridiculous.

It is a question whether you want orderly government by legitimate procedure, or whether you want to protect irresponsible, bureaucratic control. Do you want government by edict, or by orderly procedure. We have had to fight for any court review. Now it is claimed the Department is for some kind of a court review. What we are offered is a pretense instead of substance. It is a shield for the exercise of arbitrary power. The amendment presented here is skillfully designed to really prevent any legitimate and necessary court review.

It is said that there is no comparable law. As to fundamental features, that would not be true; but it is true that today we have no legitimate orderly law that provides for a practical method of testing the validity of regulations prior to their enforcement.

Recently the Supreme Court reversed a case affecting the Secretary of Agriculture, and why? The case had been pending for 7 years, and only the other day it was decided on a matter of procedure instead of passing on the merits. It was because we do not have any orderly procedure provided by the statutes of the United States such as we offer here. If this provision had been in effect, the Secretary of Agriculture would probably have had that case decided several years ago, and in his favor. He would have been provided with a clearly defined course of duty that would have saved him from the pitfall in which he finds himself. Our court-review procedure is largely based on judicial interpretation of the Constitution, without any orderly defined procedure.

* * * * *

One great trouble we have had in the formulation of this bill is propaganda. We have had innocent groups of good people used to pull chestnuts for shrewd propagandists in Washington. A wire goes out from Washington, and next day these good people, with little knowledge of what it is all about, proceed to act as if they were manikins operated by the irresponsible and concealed hand corrupting their sources of information from Washington. They permit themselves to be used to seek to intimidate or influence men in Congress to act in violation of their own better judgment.

This problem involves regulations adopted by administrative departments with the people of the United States not knowing who is writing the regulations, regulations that have the effect of a law passed by this Congress, Nation-wide in scope, for violating which a citizen may be sent to jail for as much as 3 years. Do you want such important functions performed in a perfunctory and irresponsible way, or subject to a procedure that will assure that work being done under a sense of responsibility?

In 1933, after the spraying season was partly over, news came out that certain tolerances only would be permitted. Then came the question of inspection to see whether or not the pears, or apples, or whatever the food might be, conformed. It was proposed that the farmers' fruit would be inspected at New York. He took it to the packing house in California, shipped it to New York on consignment because he could not sell it for cash, and subject to inspection at New York. If it did not conform to the requirements it had either to be reconditioned or destroyed. When you destroy a carload of fruit it means that the average small farmer in California has lost all the profits on his fruit that year. He may have figured on paying off part of his mortgage or doing something for his family, but a regulation like that if carried out would have prevented it. I sincerely hope the substitute amendment will be defeated.

[Here the gavel fell.]

The CHAIRMAN. The question is on the amendment offered by the gentleman from Michigan.

The question was taken; and on a division (demanded by Mr. Mapes) there were—ayes 34, noes 57.

So the amendment was rejected.

[p. 7898]

Mr. LEA. Mr. Chairman, I offer an amendment to the preceding section.

The Clerk read as follows:

Amendment offered by Mr. Lea: Page 82, lines 17 to 19, strike out the words "at the request of any interested industry or substantial portion thereof" and in lieu thereof insert, "or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor."

Mr. LEA. Mr. Chairman, this is the amendment that during general debate I stated I would offer. It provides that when a request is made on the Secretary of Agriculture for a hearing before him reasonable grounds shall be shown; and it is a further attempt to meet the attitude of the Department of Agriculture as to procedure under the court review section.

Mr. MAPES. Mr. Chairman, I rise in support of this amendment because it corrects in some respects the action of the committee to which the minority report called attention, and which the minority report said weakened the administrative feature of the act. I am glad to note that the majority of the committee has been converted to the views of the minority in this respect.

The CHAIRMAN. The question is on the amendment offered by the gentleman from California [Mr. Lea].

The amendment was agreed to.

Mr. LEA. Mr. Chairman, I offer another amendment which I send to the Clerk's desk.

The Clerk read as follows:

Amendment offered by Mr. Lea: Page 85, line 5, after the word "request", insert "and payment of the costs thereof."

The amendment was agreed to.

[p. 7899]

1.12a (5) (c) VOL. 83 (1938), June 10: Senate agrees to conference report, pp. 8731–8738

[No Relevant Discussion on Pertinent Section]

1.12a (5) (d) VOL. 83 (1938), June 13: House agrees to conference report, pp. 9095–9100

[No Relevant Discussion on Pertinent Section]

1.12b 1940 REORGANIZATION PLAN IV, SECTION 12, 54 STAT. 1237

Sec. 12. *Transfer of Food and Drug Administration.*—The Food

and Drug Administration in the Department of Agriculture and its functions, except those functions relating to the administration of the Insecticide Act of 1910 and the Naval Stores Act, are transferred to the Federal Security Agency and shall be administered under the direction and supervision of the Federal Security Administrator. The Chief of the Food and Drug Administration shall hereafter be known as the Commissioner of Food and Drugs.
[p. 1237]

1.12c JUDICIAL CODE, DEFINITION, AMENDMENTS

June 25, 1948, P.L. 80–773, §32, 62 Stat. 991

SEC. 32. As used in any statute of the United States:

"Circuit court of appeals" means a "United States court of appeals";

"Senior circuit judge" means "chief judge of a judicial circuit";

"Senior district judge" means "chief judge of a United States district court";

"Chief Justice" means "chief judge" except when reference to the Chief Justice of the United States is intended;

"Justice" means "judge" except when used with respect to a justice of the Supreme Court of the United States in his capacity as such or as circuit justice;

"Presiding judge" means "chief judge."
[p. 991]

1.12c (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 308, 80th Cong., 1st Sess. (1947)

REVISION OF TITLE 28, UNITED STATES CODE

APRIL 25, 1947.—Ordered to be printed

Mr. ROBSION, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 3214]

The committee on the Judiciary submits the following report in explanation of the bill (H.R. 3214) to revise, codify, and enact into law title 28 of the United States Code entitled "Judicial Code and Judiciary," and recommends that the bill do pass. The present bill has been substituted for an earlier bill (H.R. 2055) on which hearings were held and contains changes recommended by the subcommittee. [p. 1]

1.12c (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 1559, 80th Cong., 2d Sess. (1948)

REVISING, CODIFYING, AND ENACTING INTO LAW TITLE 28 OF THE UNITED STATES CODE, ENTITLED "JUDICIAL CODE AND JUDICIARY"

JUNE 9 (legislative day, JUNE 1), 1948.—Ordered to be printed

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Mr. WILEY, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 3214]

The Committee on the Judiciary, to whom was referred the bill (H.R. 3214) to revise, codify, and enact into law title 28 of the United States Code, entitled "Judicial Code and Judiciary," having considered the same, do now report the bill to the Senate favorably, with amendments, and recommend that the bill, as amended, do pass.

The purpose of the bill is to codify and revise the laws relating to the Federal judiciary and judicial procedure.

No revision of these laws has been made since 1911, and the Judicial Code enacted in that year did not include all the laws upon the subject.

A tremendous amount of additional legislation in this field has been enacted since 1911. Consequently, there is now a great mass of statutory material upon this subject, much of which is archaic, ambiguous, conflicting, and to an unascertained extent repealed by implication by later statutes. These statutes are scattered through many volumes of the Statutes at Large which are not easily accessible to the bench and bar. Moreover, many of the statutes relating to procedure appearing in the books have been rendered wholly obsolete by the Federal Rules of Civil Procedure prescribed by the Supreme Court. This situation results in the loss of much time and effort on the part of the bench and bar in determining what is the present law in this field, always at the risk of possible error.

It is evident, therefore, that a thorough codification and revision of the statutes relating to the judiciary and its procedure is very much in the public interest in order that the law in this important field may be clear, certain, and readily available.

The bill H.R. 3214 accomplishes these desirable results.

[p. 1]